# AMERICA
# *Living With*
# AIDS

*Today, I ask that this*
*Commission take back to Washington and to*
*the President my voice of hope for*
*the future and discontent with the past.*

JOHN HANNAN
*July 1990*

REPORT OF THE NATIONAL COMMISSION ON
ACQUIRED IMMUNE DEFICIENCY SYNDROME

1991

# AMERICA
# *Living With*
# AIDS

## Transforming Anger,
## Fear, and Indifference
## into Action

U.S.

REPORT OF THE NATIONAL COMMISSION ON
ACQUIRED IMMUNE DEFICIENCY SYNDROME

1991

The National Commission on Acquired Immune Deficiency Syndrome (AIDS) was established by Public Law 100-607 "for the purpose of promoting the development of a national consensus on policy concerning AIDS and of studying and making recommendations for a consistent national policy" concerning the HIV epidemic. The Commission is a bipartisan body whose members were appointed by the President, the United States Senate, and the United States House of Representatives.

Additional copies of this report are available from National Commission on AIDS, 1730 K Street, N.W., Suite 815, Washington, D.C. 20006, TDD (202) 254-3816, and from Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

# NATIONAL COMMISSION ON AIDS

June E. Osborn, M.D.
*Chairman*

David E. Rogers, M.D.
*Vice Chairman*

The Honorable
Diane Ahrens

Scott Allen

Harlon L. Dalton, Esq.

Don C. Des Jarlais, Ph.D.

Eunice Diaz, M.S., M.P.H.

Donald S. Goldman, Esq.

Larry Kessler

Charles Konigsberg, M.D., M.P.H.

Belinda Ann Mason

The Honorable
J. Roy Rowland, M.D.

*Ex Officio*

The Honorable
Richard B. Cheney

The Honorable
Edward J. Derwinski

The Honorable
Louis W. Sullivan, M.D.

# COMMISSION STAFF

Maureen Byrnes, M.P.A.
*Executive Director*

## Administration

Frank Arcari, M.P.A.
*Associate Director for Administration*

Sherell Jackson

Kerry McClurg

Carla Sharp

## External Affairs

Thomas D. Brandt, M.L.S.
*Associate Director for External Affairs*

Stacey D. Bush

Adriana Carmack

Carlton H. Lee, Jr.

Patricia Sosa, Esq.

## Program

Jane Silver, M.P.H.
*Associate Director for Program*

Nat Blevins, M.Ed.

Vicky Fujii

Jason Heffner, M.Ed.

Frances E. Page, B.S.N., M.P.H.

Joan A. Piemme, R.N., F.A.A.N.

Nicole Ryan

## Senior Writing and Research Staff

Karen Porter, Esq.

Jeff Stryker

Holly Taylor, M.P.H.

Ellen Tynan, M.A.

# CONSULTANTS

Molly Joel Coye, M.D., M.P.H.

Karen Davis, Ph.D.

Patricia E. Franks

Robert Fullilove, Ed.D.

Harvey Makadon, M.D.

## EDITOR

Linda C. Humphrey

# CONTENTS

# EXECUTIVE SUMMARY

The people of the United States have arrived at a crossroads in the history of the HIV epidemic. In the months to come they must either engage seriously the issues and needs posed by this deadly disease or face relentless, expanding tragedy in the decades ahead. In just ten years the human immunodeficiency virus (HIV), the causative agent of AIDS, has claimed more American lives than did the Korean and Vietnam wars combined. If, from this day forward, there were never another instance of new infection, the upcoming decade would still certainly be much worse. The amount of human suffering and number of deaths will be much greater.

The face of AIDS will change as well; thus far it has focused its devastation predominantly on young men. In addition, it is also a disease that affects an entire family—now, all too often, mothers, fathers, and children die swiftly, one following the other, leaving a few orphans as a grim reminder of what was once a family.

Workers on the front lines are struggling heroically to cope with illness and death, but their tools have been too few, their resources too constrained, and their logistics too crippled by the sabotage of disbelief, prejudice, ignorance, and fear.

Nor has the virus followed rules of fair play. Gay and bisexual men still bear much of the burden of HIV disease. Disproportionately and increasingly the epidemic has attacked segments of society already at a disadvantage—communities of color, women and men grappling with poverty and drug use, and adolescents who have not been effectively warned of this new risk to their futures. And with these shifts have come new anger, mistrust, and attempts to assign blame, which have drowned out the warnings that should signal the magnitude of the mounting crisis. Sadly, this has permitted too many Americans to detach from the fray, to feel the problem is that of others different from themselves, and to retreat into resentful indifference. Diversity, which should be our greatest strength as a nation, has for the moment become a weakness, and has sanctioned a begrudging and sometimes callous response. Even the language of prevention, which should be tailored to the myriad subcultures and ethnicities of people at risk, is constrained in the name of morality, withholding potentially lifesaving information and devices in order to avoid offending a public presumed to be in agreement with such constraints.

Astonishingly, even our most basic efforts to better understand and respond to this new plague have been hampered. Efforts have been made to constrain or forbid behavioral research; in the face of the most deadly sexually transmitted disease ever to confront humanity, some would prohibit even the study of the human behaviors that put our children at risk. Thus we disarm ourselves in the midst of lethal battle.

Worst of all, the country has responded with indifference. It is as if the HIV crisis were a televised portrayal of someone else's troubles. It has even appeared relatively painless; many of the torments are hidden because so many people do their suffering and grieving in secret, out of fear of stigma, discrimination, or rejection. But the epidemic will not remain painless much longer even for the most indifferent observer; soon everyone will know someone who has died of AIDS. If we are to honor our fundamental social contract with our fellow citizens, with ourselves, and with our children, we must somehow develop a sense of urgency. For there is only a little time left to recognize at a deep and fundamental level that the threat of HIV is all around us and that we must all join in this battle for the sake of future generations. In order to have any chance of winning, we must first energize our nation and transform indifference into informed action.

We have used arresting language because Americans readily understand the need to mobilize rapidly for collective action in response to external threats to life. AIDS is a life-threatening disease of global proportions, and it requires the same national resolve and commitment to address it effectively that we exhibit in times of war.

But the military analogy does not work well in this crisis. In war, we tend to look for a human enemy to attack, and alas thus far this tendency has been all too evident in our response to HIV. But in confronting AIDS, our response must be just the opposite. Compassion and concern for human suffering must direct our efforts. It is against the virus, not those infected, that this war must be waged. Tragically, to date, too many of us have failed to understand this fundamental distinction or acknowledge what a massive national effort is needed to contain the epidemic.

The sapping of our collective strength comes from many directions. There has been a dominant undercurrent of hostility toward many people with HIV disease, as if they are somehow to blame. But no one gets this virus on purpose. We do not withhold compassion from people who suffer from other diseases related to behavior. As President Bush stated in his single speech about AIDS, "Once disease strikes we don't blame those who are suffering. We don't spurn the accident victim who didn't wear a seat belt; we don't reject the cancer patient who didn't quit smoking. We try to love them and care for them and comfort them." We must replace the innocent/guilty mindset with sympathy and care for people with HIV disease.

Our nation's leaders have not done well. In the past decade, the White House has rarely broken its silence on the topic of AIDS. Congress has shown leadership in developing critical legislation, but has often failed to provide adequate funding for AIDS programs. Articulate leadership guiding Americans toward a proper response to AIDS has been notably absent. We are accustomed to hearing from the "bully pulpit" about national problems and how we should address them, so perhaps the public cannot be blamed for assuming that such a silence means that nothing important is happening. Their false calm is reinforced by politicians who declare that enough has been done about AIDS, since it is "just one disease," and that we should redirect our attention to other diseases that currently kill more people.

But we cannot turn away from what is coming, lest we be blind-sided. There are at least one million Americans silently infected with HIV. Most of them will get sick during the next decade. And in the absence of a national effort, the virus continues to spread. The cumulative deaths of the first ten years of AIDS will more than double in the next two: by the end of 1993, the toll will rise from 120,000 to over 350,000. AIDS is already the leading cause of death for young men and women in many parts of the country and is climbing relentlessly up the list of causes of "years of potential life lost."

What makes these numbers particularly tragic is that there is so much that we *can* do to turn the tide of HIV through prevention of further spread, and so much that we *must* do to provide more humane and compassionate care to those who have already been caught in the path of the virus. But there are two destructive attitudes within our borders that hamper these actions. They are a thinly veiled feeling that those who acquire the virus are getting what they deserve and a collective indifference to their fate. As long as these attitudes persist there will be reluctance to engage in the effort required to surmount HIV disease. Overcoming these attitudes will require leadership—leadership from the highest levels of government and the private sector.

To accomplish the tasks that loom ahead, we must, as a society, find a way to convert anger, fear, and indifference into informed action. We must deal effectively with discrimination and prejudice, overcome present governmental inertia, rededicate ourselves to maintaining a necessary intensity of research endeavor, educate the public to replace panic with an informed awareness of what is needed to prevent infection, and coordinate our resources to meet the urgent health care needs of the sick in cost-efficient ways that take full advantage of our powerful science. We must rec-

The cumulative deaths of the first ten years of AIDS will more than double in the next two: by the end of 1993, the toll will rise from 120,000 to over 350,000.

ognize our obligations to future generations in these tasks, for further indifference or misdirected efforts spells doom for millions.

For two years, the National Commission on AIDS has pursued its mandate from Congress to make recommendations to Congress and the President "for a consistent national policy concerning AIDS" and the HIV epidemic. We have held hearings, site visits, and consultations; we have heard from over one thousand voices across the country in direct testimony, voices that have described the horror of the HIV tragedy and the heroism of brave men, women, and children as they grapple with HIV. Some have told of their struggle with their own illnesses. Some have told of remarkable commitment to care for and about others. We have been heartened and inspired by the thousands of people throughout the land who have selflessly given of themselves to develop programs of prevention, care, and advocacy in their communities. It has been a privilege to experience the richness of diversity that could give unconquerable strength to our efforts if it were honored and fully harnessed; and it has been a source of constant sorrow to witness the accelerating loss of talent as young adults die of AIDS in ever increasing numbers.

This report attempts to address a number of the central themes that have emerged from this process. It brings out the fact that, in an important sense, the only thing new about our present quandary is the virus, that most of what we are experiencing represents old problems that have been poorly patched and bandaged or ignored entirely. The HIV epidemic did not leave 37 million or more Americans without ways to finance their medical care—but it did dramatize their plight. The HIV epidemic did not cause the problem of homelessness—but it has expanded it and made it more visible. The HIV epidemic did not cause collapse of the health care system—but it has accelerated the disintegration of our public hospitals and intensified their financing problems. The HIV epidemic did not directly augment problems of substance use—but it has made the need for drug treatment for all who request it a matter of urgent national priority. Rural health care, prison health care, access to health care for uninsured and underinsured working men and women—these issues and many more form the fabric of our concern. The report is not all-encompassing, for we have focused on certain issues that the Commission viewed as most important during our first two years of work.

The Introduction, the first chapter, paints an overview of the current status of the epidemic in America. It notes that, in endeavoring to solve problems of HIV care in the context of our current epidemic crisis, we can develop better ways to manage other chronic relapsing illnesses, innovations that will serve society well in the years to come. By taking away our right to procrastinate further, HIV presses us to confront the shortfalls in our health care system more honestly.

The second chapter deals with issues of prevention and education. It points out that prevention is currently our only hope of altering the course of the HIV epidemic and that efforts in this sector have been grossly underutilized—further, that prevention strategies will remain key even after the development of effective drugs or vaccines. It develops the theme that frank communication is our best defense for our children against the twin epidemics of HIV and drugs. Elements common to successful programs are highlighted, including the importance of cultural sensitivity, cultural competence, and community involvement. Effective progress in the prevention of HIV disease associated with illicit drug use is noted. Finally, a call is made for a comprehensive national HIV prevention initiative that would integrate federal, state, county, and municipal governments, community-based organizations, and affected populations to achieve a common goal of HIV prevention.

The third chapter discusses how health care for people with HIV disease can be improved. It takes note of the substantial progress that has been made in enhancing the quality and extending the duration of lives of people with HIV. It describes who should be involved in the delivery of health care and social services to those with HIV disease, the sites where care should be available, and how those care services can best be organized. Ideally, such care involves an interdisciplinary group in a continuum of services delivered in the least restrictive, least institutional settings at the lowest possible costs. Common elements link counseling and testing with primary care in out-of-hospital settings, coordination of that care with the hospital, access to investigational drugs and integration of illicit drug use treatment with HIV care. The point is made that existing health care providers must be better trained to manage the care of people with HIV disease and that future needs for more health care professionals must be anticipated. Finally, continued efforts must be devoted to improving communication strategies so that minimal delay occurs between development of new therapies and their availability.

The fourth chapter deals directly with the difficult issues of health care financing in the context of HIV. The Commission came to the conclusion that systemic reform will be necessary to achieve genuinely appropriate access to health care for all Americans. Only in this way will those with HIV disease be assured of needed care. Thus we have not confined our discussion to the arena of HIV disease alone, but have instead discussed solutions to problems of financing that are consistent with the broader initiatives of health system reform currently under discussion. However, our recommendations are specific to problems of HIV, and thus we offer a series of options that could improve the lot of HIV infected people and we cost out their implications. We remain firm in our conviction that these short-term measures should give way as quickly as possible to nationwide reform of the

American health care system, reform that ensures financial access to care for all of our citizens.

The fifth chapter focuses on clinical trials and treatment-related research. To date, our deliberations have not focused on the nation's vitally important biomedical research enterprise. Further, we have paused only briefly to underscore the manifest importance of social and behavioral research in achieving ultimate control of the HIV epidemic. In this chapter, the discussion is directed to currently dynamic issues of clinical trials and the search for new therapeutic agents for people with HIV disease. Problems of assuring access to drug trials for diverse populations with HIV disease while maintaining orderly studies that will permit sound scientific assessment of therapies are considered. Issues of delivery of care in the context of experimental therapy and the use of new drugs in expanded access programs are also covered.

In the sixth and final chapter, the responsibilities and opportunities for government to intervene and interact with other components of society are examined. It is noted that at all levels of government greater leadership is needed. At the federal level, we note that within the U.S. Public Health Service there has been a real effort to coordinate responses, but that there is a need for much greater cooperation and coordination across many departments at the cabinet level. State and local governmental roles are critical and distinctive. Of particular concern is the current fiscal crisis occurring in many of the states with the highest incidence of AIDS. The need to fully fund the Ryan White CARE Act is underscored, and the importance of providing the funding to evaluate programs is stressed.

After each chapter the Commission has offered a short series of recommendations for action. They have been purposely kept few with the hope that they will all receive careful consideration. They overlap. Prevention of HIV infection, care and treatment of those with HIV disease, the financing of that care, and the research necessary to improve treatment are all intimately interwoven and inseparable.

To transform what now obtains into effective action requires simultaneous attention to all facets of this epidemic which is now causing such pain and loss of life.

# RECOMMENDATIONS

1. A comprehensive national HIV plan should be developed with the full participation of involved federal agencies and with input from national organizations representing various levels of government to identify priorities and resources necessary for preventing and treating HIV disease.
2. Universal health care coverage should be provided for all persons living in the United States to ensure access to quality health care services.
3. The federal government should establish a comprehensive national HIV prevention initiative.
4. Government should assure access to a system of health care for all people with HIV disease.
5. Medicaid should cover all low-income people with HIV disease.
6. States and/or the federal government should pay the COBRA premiums for low-income people with HIV disease who have left their jobs and cannot afford to pay the health insurance premium.
7. Medicaid payment rates for providers should be increased sufficiently to ensure adequate participation in the Medicaid program.
8. Social Security Disability Insurance (SSDI) beneficiaries who are disabled and have HIV disease or another serious chronic health condition should have the option of purchasing Medicare during the current two-year waiting period.
9. Congress and the Administration should work together to adequately raise the Medicaid cap on funds directed to the Commonwealth of Puerto Rico to ensure equal access to care and treatment.
10. Policies should be developed now to address future plans for the distribution of AIDS vaccines and the ethical and liability issues that will arise when vaccines become available.
11. The federal government should fund the Ryan White CARE Act at the fully authorized level.

12. Congress should remove the government restrictions that have been imposed on the use of funds for certain kinds of HIV education, services, and research.

13. The Secretary of Health and Human Services should direct the National Institutes of Health, the Health Care Financing Administration, and the Health Resources and Services Administration to work together to develop a series of recommendations to address the obstacles that keep many people from participating in HIV-related clinical trials, as well as the variables that force some people to seek participation in trials because they have no other health care options.

14. HIV-related services should be expanded to facilities where underserved populations receive health care and human services, in part to ensure their increased participation in trials of investigational new therapies.

15. Current efforts at the National Institutes of Health (NIH) to expand the recruitment of underrepresented populations in the AIDS Clinical Trials Group should be continued and increased.

16. HIV education and training programs for health care providers should be improved and expanded and better methods should be developed to disseminate state-of-the-art clinical information about HIV disease, as well as drug and alcohol use, to the full range of health care providers.

17. Greater priority and funding should be given to behavioral, social science, and health services research.

18. The Food and Drug Administration should aggressively pursue all options for permitting the early use of promising new therapies for conditions for which there is no standard therapy or for patients who have failed or are intolerant of standard therapy.

19. The National Institutes of Health should develop a formal mechanism for disseminating state-of-the-art treatment information in an expeditious and far-reaching manner.

20. The Department of Health and Human Services should conduct a study to determine the policies of third-party payers regarding the payments of certain health service costs that are provided as part of an individual's participation in clinical trials conducted in the development of HIV-related drugs.

21. Implementation of the Americans with Disabilities Act should be carefully monitored, and states and localities should evaluate the adequacy of existing state and local antidiscrimination laws and ordinances for people with disabilities, including people living with HIV disease.

22. The federal government should expand drug abuse treatment so that all who apply for treatment can be accepted into treatment programs. The federal government should also continually work to improve the quality and effectiveness of drug abuse treatment.

23. Legal barriers to the purchase and possession of injection equipment should be removed.

24. The following interim steps to improve access to expensive HIV-related drugs should be taken:
    (a) adequately reimburse for the purchase of drugs required in the prevention and treatment of HIV disease, including clotting factor for hemophilia;
    (b) undertake, through the Department of Health and Human Services, a consolidated purchase and distribution of drugs used in the prevention and treatment of HIV disease;
    (c) amend the Orphan Drug Act to set a maximum sales cap for covered drugs.

25. All levels of government should develop comprehensive HIV plans that establish priorities, ensure consistent and comprehensive policies, and allocate resources.

26. Federal, state, and local governments should join forces with the private sector in providing long-term support to community-based organizations.

27. The U.S. Public Health Service should expand and promote comprehensive programs for technical assistance and capacity building for effective long-term prevention efforts.

28. Federal, state, and local entities should provide support for training, technical assistance, supervisory staff, and program coordination to acknowledge and support the family members, friends, and volunteers who are an integral part of the care system of a person with HIV disease.

29. The federal government should develop an evaluation and technical assistance component for all federally funded HIV-related programs.

30. Elected officials at all levels of government have the responsibility to be leaders in this time of health care crisis and should exercise leadership in the HIV epidemic based on sound science and informed public health practices.

*We must learn to practice the justice, freedoms, and compassions that we take so much pride in talking about in civics classes and teaching our children about when we tell them what it is to be an American.*

*Our response to AIDS must take into account how all people with AIDS and HIV live and recognize that we aren't all in San Francisco or New York using systems that are collapsing from the weight of us. Some of us are in Kentucky and Alabama and Missouri and Iowa, still trying to find a doctor willing to treat us or a home care agency that will send the nurse without requiring a baseline antibody test for her. . . .*

*I have to say that people living with AIDS and HIV want nothing more or nothing less than what all of you take for granted today—a place to live, the right to have a job, decent medical care, and to live our lives out without unreasonable barriers. We are not asking for extras, only to be included in what America already delivers to her privileged people.*

*I'm thirty-one this year and my life has been blessed with two healthy children—a six-year-old daughter, and a son who is almost three. Relatively speaking, I'm not in bad shape and I used to hope that I would be able to live long enough to see my children, with the help of their father, accept and adapt to the inevitability of my death. More lately I've been hoping that when I'm gone they wouldn't continue to be stigmatized by the shadow thrown by my public life.*

*But compassion is not going to happen because of a report that we make or an edict that somebody in Washington delivers. It will begin in the small towns in the quiet country throughout America when people understand that people living with AIDS and HIV are just like us because they are us.*

BELINDA MASON
*September 1989*

## CHAPTER ONE

# INTRODUCTION

Since scientists first began to understand the dynamics that govern transmission of the human immunodeficiency virus (HIV), it has been possible to predict with chilling accuracy the toll the epidemic would exact in sickness and in lives lost. As the nation enters the second decade of the HIV epidemic, the accuracy of predictions made in the mid-1980s stand as a silent rebuke. One need take only a brief look at these statistics to understand the impact that AIDS has had in the United States.

By the end of 1990, more than 100,000 people in the United States had died of AIDS, and nearly a third of those deaths occurred that year. Now more than a hundred people die in the United States every day of AIDS—one every 15 minutes—and the pace is accelerating. As of June 1991, 182,834 cases of AIDS in the United States and its commonwealths and territories had been reported to the federal Centers for Disease Control (CDC). Between March 1990 and March 1991, the reported number of new cases in the United States rose by more than one third. These numbers are a telling indication that our efforts at prevention must be redoubled.

During the earliest years of the epidemic, from 1981 to 1982, nearly 80 percent of all reported AIDS cases were from six large metropolitan areas in five states—New York City, San Francisco, Los Angeles, Miami, Newark, and Houston. So far in 1991, 31 metropolitan areas and 25 states and the Commonwealth of Puerto Rico have reported one thousand or more cumulative AIDS cases—and the number of communities, counties, and states affected by HIV disease continues to expand.

While the majority of new AIDS cases have been from metropolitan areas, there has been a significant increase in new cases in municipalities with populations less than 500,000. Lack of access to adequate health care has denied the benefits of advances in treatment to many in these smaller cities and rural communities, despite the dedication of stalwart health care providers and volunteers. More ominous still, failure to acknowledge the dimensions of the crisis has resulted in insufficient attention to AIDS education and prevention programs.

HIV disease has had a disproportionate impact on some communities. The HIV epidemic continues to affect gay and bisexual men more than any other single group of Americans; these individuals compose 64 percent of the cases of AIDS reported since the beginning of the epidemic. African-Americans constitute 12 percent of the United States population, but nearly 28 percent of AIDS cases. Hispanics constitute 9 percent of the population, but 16 percent of AIDS cases. Unless sustained support for targeted interventions that facilitate access to a broad range of health and social services is given, there is every indication that these communities will continue to be disproportionately represented among AIDS cases in the future.

> *The AIDS/HIV epidemic has focused more attention on long-standing oblems and has made it clear that it's time for sweeping olicy and systemic changes in how America cares for its most needy.*
>
> DON SCHMIDT
> *July 1990*

The number of women and children infected with HIV—particularly within communities of color—continues to grow dramatically. In fact, AIDS cases among women are growing faster than AIDS cases among men. As of June 1991, women accounted for 10 percent of all AIDS cases. In 1991 AIDS is projected to become one of the top five causes of death for young women.

Increasingly, parents who are themselves infected are forced to make agonizing choices for themselves, their infected children, and their uninfected children. Parents may sacrifice their own health as they seek care for their children and must struggle with issues of how to provide for both sick and healthy children after their death. New York City officials project an "orphan burden" of approximately 20,000 children who will need to be cared for by relatives or placed in foster homes when their parents die of AIDS in the next few years. About one fourth of these children will be HIV positive themselves. Intravenous drug use has contributed significantly to this new trend. Approximately 70 percent of all pediatric AIDS cases are directly related to maternal exposure to HIV through intravenous drug use or sex with an intravenous drug user.

Communities all across the United States are struggling to confront the twin epidemics of HIV and substance use. The nexus between HIV and substance use is unarguable. Already, approximately 31 percent of all AIDS cases can be linked, either directly or indirectly, to intravenous drug use. Cases of HIV infection related to unprotected sexual activity under the influence of crack cocaine, alcohol, or other substances is another disturbing trend, especially among adolescents. Drug treatment centers are ill equipped to deal with the growing numbers of substance users with HIV disease. The lack of treatment slots, training, and funding only perpetuates this insidious link.

The number of reported AIDS cases does not, however, accurately portray the scope of the epidemic because such figures represent only 10 to 15 percent of the total number of people now infected with HIV in the United States. CDC estimates that, at present, approximately one adult male in 100 in the United States is HIV positive and one adult female in 600 is similarly infected. In all, CDC estimates that at least one million people in this country have HIV infection.

Moreover, HIV affects people of all ages. Adolescents are often forgotten as discussions center on adults and children. Presently, adolescents with hemophilia represent a majority of reported AIDS cases among those aged 13–19. In addition, adolescents practice many of the same behaviors that put adults at risk. Given the length of time between infection and diagnosis, it is clear that the large numbers of individuals diagnosed with AIDS in their mid to late twenties were infected during their teens. The disproportionate impact of AIDS on young people is further dramatized by the "years of potential life lost." Health economists have tallied up the years of potential life lost before age 65 to describe the extent to which deaths from AIDS occur primarily in young people. In 1987 the years of potential life lost due to AIDS was 432,000. This figure compared with 246,000 for stroke, 1.5 million for heart disease, and 1.8 million for cancer. While the rates for these other major diseases remain stable, the years of potential life lost due to AIDS continues to increase. In 1991 estimates place the years of potential life lost due to AIDS between 1.2 and 1.4 million, ranking it third among all diseases. By 1992 the years of potential life lost due to AIDS will grow to between 1.5 and 2.1 million. By 1993 AIDS will clearly outstrip all other diseases in lost human potential.

HIV disease has a devastating impact on those who are already marginalized members of society. Growing numbers of HIV infection and AIDS cases occur among poor residents of inner cities. For the members of the National Commission on AIDS, the statistics of HIV disease were brought to life by the testimony of nearly one thousand witnesses at hearings and site visits across the country. The Commission met with people living with HIV disease and with caregivers on the front lines. Its members met with people at homeless shelters in New York City, at a needle exchange program in Seattle, in Native American communities in four states, in private homes in rural Georgia, at primary health clinics and drug outreach centers in Puerto Rico, at a Veterans Administration hospital in Los Angeles, and at hospitals, HIV antibody testing centers, drug treatment clinics, and comprehensive hemophilia treatment centers throughout the nation.

A mere tally of cases only sketches part of the picture. It quickly became clear during the Commission's travels that HIV disease could not be understood outside the context of racism, homopho-

*I worry about my daughter who is not infected, but affected by her family's situation. I not only worry about her, but all the siblings that are not infected because I think the system tends to forget about these children. . . . If they lose their parents, if they lose their infected siblings, the public views these children as now over the trauma. Well, those children's trauma is just beginning.*

TONI P.
*March 1991*

> *There were no support groups, no social orkers, nobody, so I retreated even further into my mmunity. But even that was rong. I had people coming to ny door wanting to beat me o—they didn't want AIDS in eir community—even though these were my relatives. . . . ut because I had AIDS I was no longer human. I was a disease. I no longer had elings. I no longer was given the opportunity to plan, to have goals, to contribute.*
>
> ILLIE BETTELYOUN, M.A.
> *September 1989*

bia, poverty, and unemployment—pervasive factors that foster the spread of the disease. This web of associated social ills has been referred to as "a synergy of plagues." Poverty and unemployment in the inner cities of the United States entail much more than an inability to pay the bills. In 1991 being poor is a generic risk factor, for it is associated with increased risks of becoming homeless, dying a violent death, and suffering and perhaps dying from a multitude of preventable illnesses. A 1990 study of mortality in New York City's Harlem found that black men in that community were less likely to reach the age of 65 than were men in Bangladesh.

The association of poverty, homelessness, and disease is perhaps best dramatized by the impact of the HIV epidemic on those in inner cities who are living at the margins of society. Without permanent addresses or steady incomes, the homeless and many of America's poor often are isolated from all but the most rudimentary health care. Public hospitals that serve low-income communities and the overwhelming majority of people with AIDS in large cities are overcrowded, their staffs are beleaguered, and their substandard funding is shrinking with each additional municipal budget crisis. Those most in need of health care are typically the ones who can least afford it. When illness strikes, the emergency room becomes the "family physician." The increase in numbers of HIV cases is placing a strain on a system already on the verge of collapse.

In some areas of the country the sheer number of people with AIDS has forced a greater awareness and understanding of the challenges people with HIV disease face. However, although recent opinion polls reflect a moderation of harsh attitudes toward people living with HIV disease, HIV-related discrimination has not disappeared. This discrimination reflects the racism and homophobia that pervade our society and, like poverty, limit people's access to care and compassion. AIDS has been sufficiently controversial to have earned the status of the most litigated disease in American history. There is, moreover, a further disquieting trend. Surveys of court cases and complaints to human rights commissions show that rather than disappearing, AIDS discrimination is changing. Subtle prejudices involving denial of basic health services are replacing overt forms of bias, and these subtle biases are more difficult to fight legally.

As the epidemic worsens, opportunities to mobilize effective responses diminish each day that we fail to act decisively. Education for prevention of further HIV spread through the avoidance of risk behavior has been greatly underutilized. Despite a slow start, there is much that can be done now to prevent new HIV infections from occurring and to enhance the quality and length of life of those already infected. In recent years there have been heartening developments in treatments for HIV disease. Guaranteeing access to all of these treatments is essential. The Commission has witnessed firsthand the efforts of many people, particularly individuals working at the community level, who are providing these and other services to people with HIV disease.

The nation must be awakened to the enormity of the HIV crisis and to the potential for individual and collective action. There is no lack of options or remedies. We are not without hope. The nation's response must be commensurate with the threat posed by the epidemic. The report that follows offers concrete proposals for action.

By 1992 the years of potential life lost due to AIDS will grow to between 1.5 and 2.1 million. By 1993 AIDS will clearly outstrip all other diseases in lost human potential.

## SELECTED BIBLIOGRAPHY

Angell, M. 1991. A dual approach to the AIDS epidemic. *New England Journal of Medicine* 324:1498–1500.

Arno, P.S., D. Shenson, N.F. Siegal, P. Franks, and P.R. Lee. 1989. Economic and policy implications of early intervention in HIV disease. *Journal of the American Medical Association* 262:1493–1498.

Bayer, R. 1991. *Private Acts, Social Consequences: AIDS and the Politics of Public Health.* New Brunswick, N.J.: Rutgers University Press.

Bayer, R. 1991. Public health policy and the AIDS epidemic: An end to AIDS exceptionalism? *New England Journal of Medicine* 324:1500–1504.

Beauchamp, D.E. 1988. *The Health of the Republic: Epidemics, Medicine, and Moralism as Challenges to Democracy.* Philadelphia, Pa.: Temple University Press.

Berk, R., ed. 1988. *The Social Impact of AIDS in the U.S.* Cambridge, Mass.: Abt Books.

Brandt, A. 1987. *No Magic Bullet: A Social History of Venereal Diseases in the United States from 1880.* Expanded edition. New York: Oxford University Press.

Brandt, A.M. 1988. AIDS and metaphor: Toward the social meaning of epidemic disease. *Social Research* 55:413–432.

Burris, S. 1989. Rationality review and the politics of public health. *Villanova Law Review* 34:909–932.

Crimp, D., ed. 1988. *AIDS: Cultural Analysis, Cultural Activism.* Cambridge, Mass.: The MIT Press.

Dalton, H. 1989. AIDS in blackface. *Daedalus* 118:205–227.

Fee, E., and D.M. Fox, eds. 1988. *AIDS: The Burdens of History.* Berkeley, Calif.: University of California Press.

Gostin, L.O. 1990. The AIDS litigation project: A national review of courts and human rights decisions. Part I: The social impact of AIDS. *Journal of the American Medical Association* 263:1461–1970.

Institute of Medicine. 1988. *Confronting AIDS: Update 1988.* Washington, D.C.: National Academy Press.

Institute of Medicine. 1988. *The Future of Public Health.* Washington, D.C.: National Academy Press.

Institute of Medicine. 1991. *HIV Screening of Pregnant Women and Newborns.* Washington, D.C.: National Academy Press.

McCord, C., and H.P. Freeman. 1990. Excess mortality in Harlem. *New England Journal of Medicine* 322:173–177.

Murphy, T.F. 1991. No time for an AIDS backlash. *Hastings Center Report* 21(2):7–11.

Shilts, R. 1988. *And the Band Played On: Politics, People, and the AIDS Epidemic.* New York: Penguin.

Wallace, R. 1988. A synergism of plagues: "Planned shrinkage," contagious housing destruction, and AIDS in the Bronx. *Environmental Research* 47:1–33.

*It's not good enough to say that we serve everyone. It's not good enough to say that our programs are open to all. If we don't specifically design our programs in such a way that they reach out into the community, that they become part of the community, and the community becomes part of them, they are not as functional as they need to be.*

*Coupled with our efforts to ensure access, representation, and inclusion is the essential work of stopping the progression of the disease through education and prevention activity, focusing on risk reduction and behavioral change. . . .*

*In communities of color, as in the majority of communities, much of the average behavior is clandestine, behind closed doors and unnamed or named differently—i.e., gay versus sex with men—so that a singular outreach strategy will only reach the most physically and obviously adverse population.*

*In our communities it is just as likely that we will reach at-risk people at church functions, at the barber and beauty shop, at the WICs program, in jail or work release, and topless clubs, in minor camps, in the social clubs, at the food bank, at the pow wow, or other community events, at the kind of local community gathering where people are together and where information flows.*

P. CATLIN FULLWOOD
*July 1990*

## CHAPTER TWO

# PREVENTION AND EDUCATION

Until a cure or a vaccine is found, education and prevention are the only hope for altering the course of the HIV epidemic. This actually understates the importance of prevention, for prevention strategies will continue to be a key component of HIV containment far beyond the advent of successful drug treatments or vaccines. There are valuable lessons to be learned from earlier experiences with sexually transmitted diseases. Effective and inexpensive treatments for many of these diseases have long been available, yet drugs alone have not stemmed the tide of infections, especially among young people and those living in poverty. Those prior experiences are underscored by the rapid reemergence of syphilis, and it can be said with certainty that medical science alone will not be able to vanquish AIDS, even with a magic bullet.

There is an urgent need for implementation of carefully designed strategies to prevent new HIV infections (primary prevention) and to prevent disease progression for HIV-infected individuals through early diagnosis, prompt treatment, and continuing care and support (secondary and/or tertiary prevention). Educational programs are also necessary to alter the public's perceptions that HIV disease is someone else's problem. The discrimination that occurs against people with HIV disease results largely from fear and ignorance, and the best weapon against these is education.

Some of the most encouraging news thus far in the HIV epidemic comes from the success of certain health education programs that have resulted in dramatic, sustained reduction in risk behavior. There is clear evidence that prevention is possible; changes in attitudes and behavior can occur as a result of carefully tailored, targeted, and credible prevention efforts. Such success is less dramatic to the public than a laboratory breakthrough, but probably more important. This chapter considers an array of education and prevention strategies, highlights some prevention success stories, and offers recommendations to focus prevention efforts for the second decade of the epidemic. As we move into the second decade, the Commission believes policies should be developed now to address future plans for the distribution of AIDS vaccines as well as the ethical and liability issues that will arise when vaccines become available.

### A DISEASE OF BEHAVIORS: CLINICAL AND EPIDEMIOLOGIC ASPECTS OF HIV

When considering prevention strategies to alter the course of the HIV epidemic it is important to keep in mind the manner in which the virus is transmitted. The limited modes of transmission of HIV have been well documented. HIV can be transmitted through sexual contact; by the sharing of contaminated injection equipment; through exposure to infected blood or blood products; and, during gestation or at birth, from an infected mother to a newborn. Breastfeeding has also been identified as a potential mode of transmission.

Understanding these modes of transmission has enabled the development of some practical strategies for use in stopping the spread of the virus. Screening of blood and voluntary deferral of blood donors at risk of HIV infection has significantly reduced the transmission of HIV through the blood supply. Sophisticated purification techniques, blood screening, and voluntary self-deferral have eliminated new HIV infections from occurring through the use of blood clotting factors to people with hemophilia. “Universal precautions” can help patients and health care workers avoid exposure to HIV. Such precautions involve the avoidance of all potentially infected blood or body fluids through barrier methods, without regard to the serostatus of patients or health care workers. The efficacy of universal precautions can be strongly inferred by a substantial drop in hepatitis B transmission (hepatitis is a hundred times more infectious than HIV). Appropriate use of condoms can decrease the risk of HIV during sexual intercourse. It is also possible to disinfect injection equipment with bleach so that the sharing of needles and syringes does not spread the virus.

In addition to the strategies available to prevent new infections, much more is now known about how to delay progression to AIDS in HIV-infected individuals. Until a few years ago, treatment regimens for HIV disease had been offered only to those exhibiting symptoms. In recent years, the clinical management of HIV disease has improved with the development of therapeutic strategies involving the use of treatments such as zidovudine (AZT) and aerosolized pentamidine for HIV-infected individuals who are still asymptomatic. This early intervention has enhanced well-being in addition to delaying the onset of AIDS, but its availability or lack thereof raises important issues of access. To bring the benefits of early intervention to people in need, additional and better coordinated services will be required—not only greater outreach, HIV testing, counseling, laboratory monitoring, medications, and primary health care, but also improved laboratory services, better coordinated systems of care, and public and private financing strategies to pay for care.

### DEVELOPING PREVENTION MESSAGES

#### Frank Talk About Sex and Drugs

Most of the disagreement about HIV prevention is not over goals, but over methods to achieve goals and over who should decide which methods ought to be used. As noted above, there are a number of simple, readily available technologies that will contribute significantly to reduction in the spread of HIV infection. Yet AIDS education and prevention efforts continue to be stymied by an unwillingness to talk frankly about sexual and drug use behaviors that risk the spread of HIV. Constraints on discussions of sex, whether imposed by law, political considerations, issues of morality, language, or culture, have been a substantial barrier to the creation and implementation of effective HIV prevention programs. There is a cruel irony at work here, for reticence about discussing sex has become an obstacle to the implementation of lifesaving prevention programs. This withholding of potentially lifesaving information raises serious ethical problems.

In the early years of the AIDS epidemic messages concerning HIV were couched in euphemisms. There were warnings about the danger posed by the "exchange of bodily fluids" when the phrase eluded public understanding. Generic, incomplete, and ambiguous messages such as this fostered misunderstandings about the actual dimensions of risk and the ways to avoid the threat posed by HIV disease.

Research in many areas of health education has shown that to encourage behavior change, prevention messages must be transmitted in a language and manner that can be understood by the people to whom they are directed. Those who design and implement education and prevention programs must be able to use unvarnished language and communications that are both meaningful and acceptable to the particular community or group being addressed. Where the communications are targeted to a specific group, the potential offensiveness to others to whom the message is not directed should not and need not be a barrier. Congress should remove the government restrictions that have been imposed on the use of funds for certain kinds of HIV education, services, and research.

> *The present situation in Puerto Rico shows the island as having such a high incidence of HIV that there exists a sense of panic about being infected. . . . Ignorance is evident at all levels of living—among employers, in public transportation, as well as funeral parlors overcharging for burials because they claim to be at risk of infection.*
>
> *I feel it is urgent to bring more forceful education throughout the island to attempt to change the attitudes of panic and rejection suffered by so many patients, to become instead an environment of faith, hope and concern.*
>
> LUIS MALDONADO
> *November 1990*

In addition to crafting clear and explicit messages that are relevant to those at risk, a greater realism is needed in approaches to altering sexual behavior and drug use. For example, although teenagers are encouraged to delay sexual intercourse until marriage or at least until adulthood, a majority of young people have not heeded such advice, regardless of how forcefully this message has been delivered. In view of this stark and dangerous reality, advice concerning abstinence must be supplemented by frank talk about AIDS, and about how to avoid sexually transmitted diseases and unintended pregnancies. In addition, it must reach children at a young age.

*When you go and talk to community people about becoming part of an AIDS project, they will say, "who is in charge?" And then they will, as we say in our community, do a reading of that person.*

ALYCE GULLATTEE, M.D., F.A.P.A.
*December 1990*

A similar set of problems has existed in discussions and attitudes about drug use as it relates to HIV transmission. The predominant policy approach has characterized drug use as a criminal rather than a public health problem. Here too the approach must be more than "just say no." A more realistic strategy is crucial to the prevention of HIV transmission related to drug use. Some of those at risk will be able to stop using drugs on their own, or will stop with the help of formal treatment, self-help, or "twelve-step" programs modeled on Alcoholics Anonymous. Access to drug treatment is an absolutely fundamental element of prevention in those populations. Those who find it impossible to stop using drugs, or who relapse following a period of abstinence from drugs, must be encouraged to practice safer sex and safer drug use and must be taught how to do so.

The Commission reiterates the recommendations made in its fifth interim report to the President and the Congress concerning the twin epidemics of HIV disease and substance use. The federal government should expand drug treatment so that all who apply for treatment can be accepted into treatment programs. The federal government should also continually work to improve the quality and effectiveness of drug use treatment. In addition, legal barriers to the purchase and possession of injection equipment should be removed. Legal barriers do not reduce illicit drug injection. They do, however, limit the availability of new, clean injection equipment, thereby encouraging the sharing of injection equipment, and the increase in HIV transmission.

### Cultural Sensitivity and Cultural Competence

As part of the need to deal realistically with issues about sex and drugs, it is critical that these subjects be addressed in a manner that is not only culturally sensitive but also culturally competent. Especially since sex and drugs are sensitive topics, it is clear that the best prevention messages will be those developed by and for the people the messages are intended to reach, through community-based efforts at the local level. It is essential to include people living with HIV disease in HIV prevention efforts. For many communities, seeing people in education and prevention efforts who are directly affected by HIV will bring home the reality of HIV and help overcome the denial that "this cannot happen to me or my loved ones." When gay men, women, people of color, and persons using drugs are not consulted in the design and implementation of prevention programs, programs directed toward these audiences will not be effective.

## STRATEGIES IN HIV PREVENTION

### The Web of Illness, Poverty, and Alienation

HIV disease is associated with a host of related health and social problems; strategies to prevent the further spread of HIV disease must take these problems into account. Other sexually transmitted diseases (e.g., syphilis, gonorrhea, chlamydia, herpes, hepatitis, and venereal warts) may act synergistically with HIV, enhancing HIV transmission or disease progression. Drug use is significantly associated with HIV disease. Injection drug use poses the most direct threat of HIV transmission when contaminated injection equipment is shared; this is a risk for intravenous users of any drug, including heroin, cocaine, and steroids. It has been less widely recognized that crack cocaine, alcohol, and other psychoactive drugs also represent serious threats when multiple sexual partners and impaired judgment about risk are involved.

From New York City to Waycross, Georgia, from San Juan, Puerto Rico, to Seattle, Washington, in hearings and site visits the Commission has seen how poverty, homelessness, lack of basic health care, lack of prevention services, and lack of drug treatment combine with the alienation experienced by gay men, poor women of color, and drug users to exacerbate the spread of the virus. A dramatic example of this is the increase in sexually transmitted diseases in many urban and rural areas in the United States.

### Essential Elements of Prevention Programs

To intervene effectively in the spread of HIV it is essential to consider the broader social context of the HIV epidemic, for it involves not only individuals at risk, but also families, cultural and social groups, neighborhoods, and communities at risk of multiple problems. Although this adds to the complexity of HIV intervention, it also means that successful HIV prevention efforts will not only reduce the spread of HIV, but also are likely to have an impact on the rates of other sexually transmitted diseases, teenage pregnancy, and drug use.

*It's hard to educate a woman who is homeless and hungry.*

SANDRA VINING-BETHEA
*January 1991*

A mix of strategies is being used throughout the country in the design of HIV prevention programs. From grass roots efforts to federally sponsored programs, these varied approaches draw on a number of different fields, disciplines, perspectives, and experiences. The potential for success in prevention is enhanced by government policies that are not restrictive and that create a climate in which prevention efforts can be creative, cooperative, and comprehensive. Other interventions that have helped to create a positive context for HIV prevention efforts include laws guarding confidentiality and protecting against discrimination. Without assurances that people can avail themselves of HIV prevention opportunities without risking the loss of jobs, housing, and health insurance, it is next to impossible for prevention and education services to reach those at greatest risk of HIV.

If prevention efforts are to be successful they require sustained commitment to change over the long term, rather than an expectation of short-term results. They also require support of multiple interventions and strategies, rather than investment in a single "solution." Support must be continuous and predictable. Prevention programs must be accountable, progress and results must be measurable, and training and support must be provided to those administering the programs.

Some important prevention strategies include: sex and HIV education appropriate to age levels; treatment programs for substance users; education about bleach and clean needle and syringe programs for those who are unable to stop using drugs; efforts to control sexually transmitted diseases; outreach programs to provide contraception to women of childbearing age; easily accessible HIV antibody testing and essential counseling; peer counseling; street outreach efforts; and readily available condoms supported by a social marketing program that encourages their use.

### Individual and Community Approaches

Efforts designed to control HIV infection create change by intervening at many levels. Technological approaches will not work without changes in knowledge, attitudes, beliefs—and behaviors. In this second decade of the HIV epidemic, there will be an increasing need to supplement individual behavior change strategies with a concept of communitywide prevention. Similar interventions aimed at changing the norms of entire communities are among the most promising HIV prevention strategies. These interventions have proven to be effective in promoting a variety of health behaviors, such as family planning and cardiovascular risk reduction, including smoking cessation.

Communitywide models of HIV prevention make use of a mix of strategies. Communities of interest are defined by more than mere geographical proximity. Communities may be defined by:

- *common identities* such as gender, sexual orientation, race or ethnicity, language, religious affiliation, age group, or a genetic condition such as hemophilia;
- *behavior* such as same-gender sex, injection drug use or needle shar-

ing, and non-injection drug use, including alcohol use;

- *location or setting* such as hospitals, clinics, prisons, churches, work environments, and schools;
- *other circumstances* such as possible exposure to HIV infection through blood transfusions or other use of blood products.

Communitywide models are designed to utilize multiple settings, channels, and organizations in their design, implementation, and evaluation. Each community has distinct features; no two communities will be alike in their response to HIV disease, and thus the process by which a response to the HIV epidemic is mobilized in communities will also vary. Understanding more about how to respond to AIDS involves understanding and respecting what the community regards as problems and priorities, acknowledging social organization and structure, and then identifying the community's available resources and what solutions it will be ready to employ. These efforts must be supported, funded, documented, and evaluated to broaden the reach of our prevention efforts. Federal, state, and local governments should join forces with the private sector in providing long-term support to community-based organizations. As a part of this effort, the U.S. Public Health Service (PHS) should expand and promote comprehensive programs for technical assistance and capacity building for effective long-term prevention efforts.

## REDUCING SEXUAL TRANSMISSION OF HIV

Substantial progress has been made in reducing sexual transmission of HIV infection among certain populations in some areas of the country. Nevertheless, sexual transmission of HIV continues to be a major route of infection. Although many more people are now aware of the types of sexual behaviors that risk the spread of HIV, the gulf between awareness of risk and long-term behavioral change can be wide. Sexual conduct is influenced by complex factors, including biological drives, religious beliefs, customs, and cultural and community norms and values. These aspects of sexual behavior make changes difficult to inculcate. Consider how difficult it is to get people to stop smoking, even when they know how dangerous it is; or how much effort it has taken to encourage people to wear seat belts, despite the manifest risks of not doing so. A psychiatrist who testified before the

*"¡No mueras por ignorancia!" (Do not die because of ignorance!); "La Familia Hispana Contra el SIDA" (The Hispanic Family Against AIDS); "Informe SIDA" (AIDS Bulletin); HACER (The Hispanic AIDS Committee for Education and Resources); Proyecto "Vecino a Vecino" (Neighbor to Neighbor Project); "Iluminate. ¿Como vas a manejar? ¿Vivo o muerto?" (Know Yourself. How will you manage? Dead or Alive?); "Las Almas de Dios" (the Souls of God); "Noche de Ronda" (Night of Serenades); "La Clínica Esperanza" (Clinic of Hope); CURAS, Comunidad Unida en Respuesta al SIDA (Community United in Response to AIDS).*

*These and many more are the collective response of the Latino/Hispanic community's fight against AIDS in this country.*

ADOLFO MATA
*March 1991*

Commission made a telling comparison: "We are essentially asking people to go on a diet and never cheat for their entire life. Unlike a diet, cheating may be lethal."

## Same-Gender Transmission

Homosexual and bisexual men still bear much of the burden of HIV disease in the United States across all racial and ethnic groups. In cities with large gay communities, such as San Francisco and New York, a substantial portion of gay men are infected with HIV. The validity of programs of prevention is dramatically underscored by studies in the last several years of white gay men in urban epicenters of the HIV epidemic. Sustained changes in sexual behavior have been accompanied by a marked lowering of the rate of incidence of new infections. Interpretation of these trends is further supported by stable or falling rates of sexually transmitted diseases.

> *What honor*
> *can there be in being a hero in*
> *losing battle? History teaches*
> *us that those who exhibit valor*
> *on behalf of the conquered*
> *become forgotten. There's an*
> *increasingly large body of*
> *evidence that suggests that*
> *those of us who are ourselves*
> *nfected with the HIV virus are*
> *already forgotten, especially if*
> *we are black and gay or*
> *bisexual.*
>
> PHILL WILSON
> *January 1990*

A dramatic change in peer behavioral norms among gay men is one of the heartening stories of the HIV epidemic. Early in the epidemic, programs were established to impart information, to help motivate change, and to bolster skills necessary to change behavior, such as ways to negotiate safer sex. Many of these programs came from within the gay community and relied to a large extent on volunteers, as many governmental agencies were not confronting the epidemic. The result of these programs was that many gay men increased condom use, adopted safer sex practices, and reduced the number of their sexual partners.

Although many gay men have made remarkable changes in sexual behavior, these changes should not be taken as evidence that the job of education and prevention *has* been done, but rather that it *can* be done. There are many men who engage in same-gender sex but do not perceive of themselves as being gay or as belonging to any gay social or political community. These men are particularly difficult to reach with gay-specific HIV prevention messages. Targeted messages about behavior change may have passed them by. In addition, as the epidemic matures, sustained efforts will be necessary to prevent "relapse" among gay men who have made changes in their sexual behavior. More attention to the relationship between alcohol and drug use and sexual behavior is warranted, as those who combine sex with alcohol and other drugs are more likely to engage in sexual activities that carry a high risk of HIV transmission.

Gay and bisexual men are the largest segment of people with AIDS among blacks and Hispanics (36 and 40 percent of cumulative cases, respectively, as of June 1991). A total of 28 percent of gay and bisexual men with AIDS are black or Hispanic. Despite these realities, epidemiologic and behavioral studies in HIV disease had until recently focused overwhelmingly on white gay men. Gay men of color may face special risk-reduction challenges. More must be done to reach out to these men and empower them through prevention efforts.

Women who have sex with other women have been neglected in HIV prevention efforts. The lack of attention to this group of women is due in part to a tendency toward rigid categorization that belies the true variety of human sexual experience. Lesbians are still viewed by many in terms of their status as members of a group rather than the behaviors they may practice and thus are often overlooked in prevention efforts. Many of these women may have a false sense of security about their risk of HIV infection and consequently neglect to practice safer sex habits. Lesbians must be given information about how to reduce the risk of HIV transmission and must be encouraged to practice safer sex with both female and male sexual partners and to use safe injection procedures if they use injection drugs.

Adolescents who are just entering a phase of sexual experimentation or who are beginning to express their sexual identity may be at special risk for HIV infection. The well-known tendency of teenagers to deny risk is abetted in the case of gay youth by the lengthy incubation period of the AIDS virus—as many as five to ten years may pass between infection with HIV and development of clinical symptoms. Approximately 20 percent of AIDS cases have occurred among individuals aged 20 to 29; most of these people were probably infected during their teenage years. Gay males in their teens and twenties outside urban epicenters of HIV are significantly more likely than older men to engage in unprotected anal intercourse and to do so with more partners, according to current studies reviewed by the Committee on AIDS Research and the Behavioral, Social, and Statistical Sciences of the National Research Council. Young gay men often wrongly perceive the risk to be solely from older men, deriving a false sense of security from having sex with other young men who appear healthy, but who actually may be HIV infected.

### Heterosexual Transmission

Over the past few years concern over AIDS cases in the United States attributed to heterosexual contact has grown. Cumulatively, 6 percent of all AIDS cases in the United States are due to heterosexual contact. In this exposure category, women are at greater risk than men of acquiring infection through heterosexual contact. Thirty-three percent of all

Thirty-three
percent of all
women with AIDS
as opposed to
2 percent of all
men with
AIDS report
exposure through
heterosexual
contact.

women with AIDS as opposed to 2 percent of all men with AIDS report exposure through heterosexual contact. It is important to note that a majority of female heterosexual cases are related to unprotected sex with an HIV-positive intravenous drug user. Women of color have been particularly heavily affected.

These statistics are particularly troubling because many women believe they are not at risk and do not need to practice safer sex or change potentially dangerous behaviors. Prevention messages are not effectively reaching large populations of women. Much of the attention women have received in the HIV epidemic has been related to the potential for the spread of HIV to their sexual partners or offspring; women are frequently characterized, explicitly or implicitly, as "vessels of infection" or as "vectors of perinatal transmission." Women need attention in their own right, not only in the development and evaluation of HIV prevention strategies, but in all aspects of HIV policy development.

Many prevention messages have not been grounded in the realities of women's lives. Not surprisingly, such messages have not been very effective. Perhaps the most unrealistic prevention message for women is the nearly exclusive focus on the use of condoms, advice that is naive regarding anatomy, gender roles, and power relationships. The emphasis on condoms grew out of the early years of the HIV epidemic when sex between men was a predominate concern. As more knowledge has been gained about the epidemic, the need for alternative prevention methods has been clearly indicated. Condom use requires the active involvement of the male partner, and the woman must secure his cooperation or convince him to terminate the sexual interaction if he refuses. The use of condoms may be complicated by the perception that their use is an admission of infidelity, hence threatening relationships of long standing. In fact, many men report using condoms "on the side," but not in their primary relationships.

That condom use is inherently limited as a method for preventing the heterosexual spread of AIDS does not imply that attempts to encourage their use should be abandoned, but rather that such efforts should be redoubled. The United States has yet to embark on campaigns such as have been undertaken in other countries to foster fundamental changes in social attitudes about condoms, through advertising, social marketing, and intensive outreach and reinforcement strategies.

*I am twenty-one years old. I have hemophilia and am HIV positive. I found out my HIV status when I was fourteen—when they thought it could mean was immune. It didn't really matter what they thought then anyway. Death means absolutely nothing to a fourteen-year-old. I thought was immortal until just about a year ago when my girlfriend at the time and I were going to find out the results of her first AIDS test. Meanwhile, most of my friends still think they are immortal. This is one of the basic tricky aspects of AIDS for the adolescent and the young adult. It is extremely hard to have a mid-life crisis and acknowledge the fact that you are going to die when life has just begun. The other is the act that this acknowledgement of death comes through something that is the reaffirmation of life and love—sex.*

T. H.
*April 1991*

Across categories of exposure, individuals for whom condoms might reduce risk report only limited consistent use of them. Condoms must be made more widely available and information on how they can be effectively used must be provided. Further, their use must be promoted through sophisticated social marketing strategies. The de facto ban on network television advertising of condoms continues to impede their social acceptability. These and other impediments to the use of condoms should be recognized and addressed. More behavioral research is needed to develop methods of HIV prevention during sexual contact that are acceptable to both women and men.

While attempts to promote greater use of condoms to reduce transmission of HIV should continue, it is equally important that research funds and personnel be devoted to the exploration of alternative methods of preventing HIV transmission. Increased efforts are necessary to develop a wider array of chemical and physical barriers to block vaginal HIV transmission that do not depend entirely on the male partner's cooperation. These include gels, suppositories, or sponges that might be used before or after intercourse. More research is needed on chemicals that kill viruses (virucides). A female condom is also in development. The diaphragm should be evaluated in terms of its potential role in HIV prophylaxis.

In considering alternatives to condoms that might be more relevant for women, it is important to consider not only *efficacy* (the probability of preventing HIV transmission given optimal or correct use of a prevention technique or device), but also *effectiveness* (efficacy plus the extent to which the device or technique will be used correctly and therefore contribute to a slowing of the epidemic). Even surefire methods of prevention are worthless unless people are willing to use them.

Teenagers tend to deny risk. Yet, even when they recognize the risks of HIV, many adolescents still feel they are invincible or discount the risk of HIV because other risks in their environment are perceived as greater and more immediate. Adolescents are at risk, not only from their own perceptions of lack of risk, but also because adults often ignore the special needs of adolescents or deny that adolescents are sexually active.

> *The hopelessness that is connected with adult life for young minority people is a future of which they are aware. If we don't change the fact that they have no hopeful future, I'm not sure we can take the pressure off the wish to find whatever joyous escape exists in the present.*
>
> MINDY FULLILOVE, M.D.
> *March 1991*

Abstinence is an efficacious means of eliminating the risk of sexual transmission of HIV. However, although many young people have been encouraged to delay intercourse until marriage or adulthood, some teenagers will choose to begin sexual behaviors during adolescence. In fact, studies in 1988 revealed that by age 15, 27 percent of girls and 33 percent of boys were sexually active. Half of girls had had sex by age 17 and half of boys by age 16; three out of four unmarried 19-year-old women and five out of six unmarried 19-year-old men had had sexual intercourse.

Moreover, unprotected sexual activity is clearly occurring among teen- agers. Other clear evidence for adolescent sexual behavior is found in the high rates of sexually transmitted diseases among sexually active adolescents and the fact that approximately one million teenage girls become pregnant each year. According to a study conducted by the National Research Council, entitled *Risking the Future*, more than 400,000 of these pregnancies occurred in young women 15–17 years of age. Pregnancy still remains the focus of many health and sex education programs. If birth control is the sole objective, an oral contraceptive may be used instead of a barrier method that would also help to prevent HIV and sexually transmitted diseases. Some young women practice anal or oral sex as a birth control method, which may pose increased risks for transmission of HIV. Education messages to young women and men must be twofold, teaching ways to prevent both pregnancy and disease.

> *We have over*
> *venty identified Asian/Pacific*
> *ommunities here in southern*
> *alifornia. We speak different*
> *nguages. We come from very*
> *different cultures, ethnic*
> *backgrounds. Language is a*
> *arrier for us, not just English.*
> *long with language, we have*
> *cultural barriers—gan-barr,*
> *he barrier of denial, bringing*
> *shame to the family.*
> *Homophobia and/or*
> *omoignorance. These are all*
> *issues and barriers that exist*
> *within our community.*
>
> DEAN GOISHI
> *January 1990*

Adolescents need clear, realistic, unequivocal prevention messages about the risks of HIV transmission associated with unprotected sexual activity, sharing of injection equipment, and sexual activity in conjunction with substance use. Adolescents must also be provided with the tools necessary to engage in safe behaviors. Adults must use their knowledge to impart information despite their own embarrassment or reluctance to discuss sex.

Although many adolescents practice risk behaviors, some have a more difficult time than others finding information or avoiding risk behaviors. These adolescents need targeted programs. Some studies have shown African-Americans, Hispanics, and other youth from communities of color to be less aware of what places them at risk for HIV transmission than white youth. Special attention should be given to these communities. Young people who are infected with the virus need counseling and education to deal with the difficulties of living with HIV disease.

### Sexual Transmission Related to Substance Use

Sexual transmission of HIV related to substance use concerns sexually active individuals, whether gay, lesbian, or heterosexual, whether adult or adolescent. Injection drug use is clearly linked to sexual transmission of HIV. It is less well known that sexual activity in conjunction with the use of other psychoactive substances, including alcohol and crack cocaine, poses a substantial risk. Sexual transmission with regard to substance use occurs when judgment about safer sex is impaired as well as when sex is traded for drugs.

Prevention messages about sexual behavior as well as drug use may be effectively conveyed in drug treatment programs. Unfortunately, drug treatment opportunities, deficient for men, are in even shorter supply for women. This problem is in part a continuation of prior inequities, for women have traditionally had difficulty gaining access to drug treatment facilities, which for the most part have been oriented toward the needs of men. Women with children and pregnant women who use drugs often have special difficulty finding drug treatment that meets their needs. Women in need of treatment are often single parents who attend to their children's needs before their own. Even when pregnant drug users are accepted into treatment, a significant opportunity for intervention may be missed, since there are often no provisions for prenatal care.

Sexual partners of individuals who use intravenous drugs are often unaware of the risks they face, either because their partner's drug use is covert, or part of the past, or because they are unaware of the associated risks of HIV. Those who are aware of the risks may still face difficulty in seeking counseling for risk reduction. Thus, the simple steps that must be taken to prevent AIDS, such as condom use, may not be so simple after all.

Adolescents may be at heightened risk for transmission through sexual activity in conjunction with the use of substances other than injection drugs. While some studies indicate that adolescents may avoid intravenous drug use, the use of alcohol and the growing use (especially in low-income urban communities) of crack cocaine places these individuals at increased risk. It is extremely important, therefore, not to assume that intravenous drug use is the only link between drugs and sexual transmission.

### [illegible]

Successful and sustained risk reduction among injection drug users is vital to slowing the spread of HIV infection. Injection drug users place themselves at risk through a variety of behaviors, and may spread the virus not only to their needle-sharing peers, but also to their sexual partners and at birth to their offspring. Hence, any potentially successful program must address drug use and sexual behaviors simultaneously. It is also important to provide prevention education to all those who engage in the risk behavior of sharing injection equipment, including athletes who inject steroids and individuals who inject vitamins and medications.

Although there is a commonly held misconception that drug users in the throes of addiction are impervious to messages about the risk of HIV trans-

*What do we do now? We do what many cities have been doing for several years now. We take it to the street. We take reatment to the user. We take intervention to the user. We take education to the user. We take prevention to the children and families. Prevention is all of the above. We take hope to people who have no hope. We become advocates. We become ransportation. We bring food nd clothing to those who have no food and clothing. Ve let the user, the addict, and the persons living with HIV and AIDS know that we truly care. We open doors for them that previously were shut—treatment doors, mergency care doors, medical care doors, and whatever doors remain locked.*

EDMUND BACA
*January 1991*

mission, the evidence suggests otherwise. Drug users know a great deal about how HIV is transmitted and are willing to make the changes necessary to reduce risk of transmission when encouraged to do so. There is evidence that HIV prevention strategies targeting injection drug users can result in decreased needle sharing, increased needle cleaning, increased demand for sterile needles on the street, and stable or declining seroprevalence rates among drug users. In addition, when such HIV-related interventions are offered, there is often an increased demand both for treatment for addiction and for primary care.

Some consistent messages have emerged from studies of the impact of HIV on drug use behaviors. Most drug users report changing their behavior in response to AIDS. There is no single method of reducing HIV risks that will work for all drug users; prevention strategies must encourage both cessation of use and the adoption of safer injection practices for those who continue use. Finally, more drug users have reported changes in drug use practices than changes in sexual behaviors, and yet, of course, both are essential. Thus, renewed efforts to encourage behavioral changes related to both sex and drug use are necessary.

HIV associated with drug use has potential for extremely rapid spread. Some cities have already experienced this, with up to 50 percent of intravenous drug users HIV seropositive. In other cities with large populations of intravenous drug users, HIV seroprevalence remains at much lower levels. The geographic variation in HIV seroprevalence among intravenous drug users underscores the opportunities for heading off the spread of HIV disease. HIV prevention strategies targeting injection drug users now include clinic-based interventions, street outreach projects, community-based information and awareness campaigns, and both publicly supported and unsanctioned needle exchange programs.

As the Commission noted in its recent report, *The Twin Epidemics of Substance Use and HIV,* the unmet need for treatment on demand is critical. In cities hard hit by both drug use and HIV disease the situation is extremely serious. New York City, for example, has an estimated 200,000 intravenous drug users, approximately half of whom are HIV positive. Yet New York has only 38,000 publicly funded drug treatment slots. Outreach efforts have had the positive side effect of referring individuals to treatment programs, but these gains will be lost if there are not enough treatment slots available.

Among the most important AIDS prevention efforts are those aimed at encouraging injection drug users to adopt safer injection practices, either by using bleach or by participating in needle exchange and distribution programs. These programs have frequently been delayed or blocked by political and community opposition and by laws that make possession of drug injection equipment a criminal offense. In some localities, criminal justice officials have looked the other way as local public health officials and activists have mounted needle exchange and distribution programs. On occasion, local prevention activists charged with crimes for distributing clean needles have defended their actions in court, claiming that any violations of law in distributing clean needles were justified by the need to save lives. This was borne out in the recent decision of a Manhattan judge who overturned criminal charges against AIDS activists engaged in distributing sterile needles by stating, "The nature of the crisis facing the city, coupled with the medical evidence offered, warranted the defendants' action." Courts in Massachussetts and California have also failed to convict people conducting needle exchange programs.

Fears that needle and syringe exchange and distribution programs might encourage drug use and create a new class of drug injectors have not materialized. Where such programs have been operating, they have provided a means of encouraging injection drug users to join treatment programs. Needle and syringe distribution programs deserve further experimentation, and laws and regulations that block implementation and study of such programs should be repealed.

[illegible]

HIV prevention strategies and messages for women who wish to consider becoming pregnant may have to be quite different than those for women who are willing to delay having children. Issues of disease prevention are often conflated with questions of pregnancy and reproductive choice. A number of steps aimed at preventing pregnancies, such as vasectomies, intrauterine devices, and oral contraceptives, may have little or no impact on interrupting the spread of HIV disease.

In recent years there has been much debate about whether HIV antibody testing of pregnant women or newborns ought to be mandatory, routine, or merely available. The backdrop against which these debates are taking place is a set of clinical studies that reveal that transmission of the virus from HIV-positive mothers to newborn children is less than previously thought, approximately 30 percent or less. HIV antibody testing of newborns only definitively establishes whether the mothers are HIV positive. Newborns who test HIV positive may or may not be infected. Some will test positive only because of the presence of maternal antibodies that will eventually disappear. Debates have centered on whether testing or screening ought to involve all pregnant women or merely those at "high risk" of HIV and the extent to which counseling ought to be

ew York City,
has an estimated
200,000
intravenous drug
users, approximately half of whom are
HIV positive.
Yet New York has
only 38,000 publicly funded drug
treatment slots.

directive in discouraging HIV-infected women from becoming pregnant or bearing children. HIV antibody screening of pregnant women and newborns raises profound moral, legal, and policy issues that are dealt with at considerable length in recent reports on the subject by the Institute of Medicine (1991) and other policy groups.

> *The medium is the message. You can't have safe sex at Cabrini Green Projects. It's not a safe place.*
>
> MICHAEL JAMES
> *March 1991*

All women of childbearing years who are considering pregnancy or are pregnant must be apprised of all the options available to them—they must be informed of their options but not coerced into any particular decision. Just as much of the advice to date for women about how to prevent the sexual transmission of HIV may have been of little relevance to their lives, there is a growing realization that blanket advice for HIV-positive women to avoid becoming pregnant may not be appropriate. As noted in a report by the Institute of Medicine, *HIV Screening of Pregnant Women and Newborns*, ". . . limited studies to date offer little evidence to suggest that knowledge of HIV infection status significantly affects women's decisions regarding continuation of a pregnancy or future childbearing." For many women, having children is a large part of being a woman; thus, fully informed women may decide that it is worth running the risk of perinatal transmission to give birth.

## RESEARCH AND EVALUATION REGARDING PREVENTION PROGRAMS

During the first decade of the HIV epidemic the need for epidemiologic and behavioral research was recognized. The published literature that resulted consists primarily of a mosaic of small-scale studies, examples of behavioral interventions demonstrated to be effective either in reducing new HIV infections or in making substantial modifications to high-risk behaviors in narrowly defined populations. In the earliest phases of the epidemic, a great deal was learned about appropriate prevention strategies among those identified to be at risk, especially white, self-identified gay men in urban areas.

There remains, however, a lack of knowledge in several areas crucial to education and prevention—sexual and other behavior patterns in people of varied cultural, racial, and ethnic groups; frequency of different types of sexual behavior among adolescents or adults; family or community approaches to prevention; technological approaches to prevention, including female-based research on virucides and barrier methods of prevention; large-scale studies of needle exchange programs in the United States; and innovative approaches in prevention, including communitywide approaches.

Greater priority and funding should be given to behavioral, social science, and health services research. Social marketing and communications research are also necessary to find out whether national mass media campaigns, such as CDC's "America Responds to AIDS" campaign are effective, among what groups, and for what purposes. The number of racial and ethnic minority health professionals must be increased. Every effort must be made to identify, nurture, and support researchers indigenous to the community.

It is critical that researchers clearly establish what does and does not work in prevention. The cost of not knowing will be measured not only in dollars spent and opportunities missed, but also in lives lost. Future prevention efforts are greatly hindered by insufficient evaluation of HIV prevention services and programs within CDC and other federal agencies, as well as within local communities. The National Research Council (NRC) has proposed an evaluation strategy based on three key questions:

1. What interventions are actually delivered?
2. Do the interventions make a difference?
3. What interventions or variations work better?

As NRC notes, "The evaluation of AIDS intervention programs is not an easy task: it will take time, and it will also require a long-term commitment of effort and resources. . . . The nature of the HIV/AIDS epidemic demands an unwavering commitment to prevention programs, and ongoing prevention programs require a similar commitment to their evaluation." NRC recommends a full complement of evaluation research, encompassing formative, process, and outcome evaluation (NRC, 1991).

The Commission agrees that evaluation is needed at every step of development and implementation of HIV prevention programs. Participatory evaluation—which includes groups targeted by the programs and groups providing the programs, as well as funding agencies—is a critical aspect of evaluation that has been frequently overlooked. Communities should not be viewed by academic evaluators as a place for experimentation without consultation or collaboration. There is a need for greater collaboration among federal agencies, especially CDC and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), related to research and evaluation strategies and HIV prevention. The federal behavioral research establishment has an important role to play in "meta analysis"—the collation and comparison of various small-scale research studies. It can also provide mechanisms so that those responsible for the development of prevention programs can be kept abreast of the latest developments.

But even the best efforts to increase the knowledge base and to improve information dissemination strategies will be for naught if the knowledge gained is not effectively applied.

Unfortunately, the findings of research on HIV education and behavioral interventions are only partially applied because of restrictions placed on prevention messages by the U.S. Congress. In the area of prevention, it is also important that the United States consider adopting successful prevention models developed in other countries. Examples would include sexual education programs in Scandinavia that have led to low rates of sexually transmitted diseases and unintended pregnancies (though rates of sexual activity are comparable to the United States) and programs of over-the-counter sales of needles and needle exchanges throughout Europe and Australia that have reduced needle sharing without leading to increased intravenous drug use.

### A COMPREHENSIVE NATIONAL HIV PREVENTION INITIATIVE

The federal government should establish a comprehensive national HIV prevention initiative that integrates the approaches of federal, state, county, and municipal government; community-based organizations; the private sector; and affected populations. This strategy should ensure both central coordination and local autonomy. At the federal level, a plan should be established within the Public Health Service and across other federal agencies to coordinate development of effective HIV prevention programs, rather than allowing each agency or institute to pursue potentially idiosyncratic activities. Emphasis should be placed on linking health care and prevention efforts. The Commission stresses the urgent need for implementation of carefully designed strategies to prevent new HIV infections and to prevent disease progression for HIV-infected individuals through early diagnosis, prompt treatment, and continuing care and support. Offering advice about changes in behavior and making referrals to education, counseling, and prevention services is a critical aspect of delivering HIV care.

Although some states and localities have built infrastructures to enable them to mount effective primary and secondary prevention programs, others have not. Community-based organizations, often the heart of primary prevention efforts, are even less likely to have the strong administrative and fiscal structures that would ensure that their programs remain sound. Many community-based organizations have relied upon seed money or demonstration grants from governmental or private foundation sources. The fragility of funding streams has made it difficult to plan, implement, and evaluate programs, especially for newer groups in minority communities. Rigid requirements hinder attempts to develop and sustain meaningful programs. Delayed reimbursements jeopardize the very existence of community-based organizations, which are a critical element of HIV prevention activities nationwide.

Communities must find better ways to mobilize, plan, design, and implement comprehensive communitywide HIV prevention efforts. Public health departments, community-based organizations, and affected populations must be able to work through and resolve conflicts. CDC, the Health Resources and Services Administration, ADAMHA, states, county and municipal governments, and community-based organizations need flexibility in funding. The concept of HIV care consortia, as in the Ryan White CARE Act, merits consideration in HIV prevention efforts. The National Institute of Mental Health's model for mobilizing communities around issues related to the severely mentally ill may be another potential model.

The primary and secondary prevention of HIV disease deserves a place on everyone's agenda. It is within our capacity as individuals, as members of various communities, and as a nation to halt the further spread of HIV and to extend and enhance the quality of life for those already infected. We must learn to draw upon our diversity in order to bring people together to confront the challenges posed by HIV.

# RECOMMENDATIONS

1. **The federal government should establish a comprehensive national HIV prevention initiative.**
   This initiative should be authorized by Congress and developed by the Department of Health and Human Services. It should provide flexible resources to state and local government and other public or private nonprofit entities for communitywide HIV prevention efforts. It must also include input from individuals who have expertise through experience, education, or training. The prevention initiative is an essential component of a national HIV plan.

2. **Greater priority and funding should be given to behavioral, social science, and health services research.**
   Behavioral, social science, and health services research are currently grossly underfunded. The Commission believes there must be a more appropriate balance of funding between these areas of study and biomedical research.

3. **Congress should remove the government restrictions that have been imposed on the use of funds for certain kinds of HIV education, services, and research.**
   Government restrictions on certain HIV programs and on behavior-oriented research studies impede the fight against HIV disease. HIV prevention programs and research into sexual and drug using behaviors must be conducted and evaluated. Results from these and other health promotion and disease prevention efforts must be shared and rapidly incorporated into HIV prevention and education strategies.

4. **The U.S. Public Health Service should expand and promote comprehensive programs for technical assistance and capacity building for effective long-term prevention efforts.**

5. **Federal, state, and local governments should join forces with the private sector in providing long-term support to community-based organizations.**
   Community-based efforts are now and will continue to be an integral part of any HIV prevention strategy. The role of people with HIV disease must be recognized, encouraged, and supported. In designing services, community-based organizations and their programs must be accountable, yet they must be afforded sufficient flexibility to implement programs that will best serve communities in need.

6. Policies should be developed now to address future plans for the distribution of AIDS vaccines and the ethical and liability issues that will arise when vaccines become available.

7. The federal government should expand drug abuse treatment so that all who apply for treatment can be accepted into treatment programs. The federal government should also continually work to improve the quality and effectiveness of drug abuse treatment.

8. Legal barriers to the purchase and possession of injection equipment should be removed.
   Legal barriers do not reduce illicit drug injection. They do, however, limit the availability of new, clean injection equipment, thereby encouraging the sharing of injection equipment, and the increase in HIV transmission.

## SELECTED BIBLIOGRAPHY

Amaro, H. 1991. *AIDS/HIV Related Knowledge, Attitudes, Beliefs and Behaviors Among Hispanics in the Northeast and Puerto Rico.* Study conducted by the Northeast Hispanic AIDS Consortium. Boston, Mass.: Boston University School of Public Health.

Bandura, A. In press. A social cognitive approach to the exercise of control over AIDS infection. In R. DiClemente, ed., *Adolescents and AIDS: A Generation in Jeopardy.* Newbury Park, Calif.: Sage Publications.

Bayer, R. 1991. *Private Acts, Social Consequences: AIDS and the Politics of Public Health.* New Brunswick, N.J.: Rutgers University Press.

Becker, M.A., and J.G. Joseph. 1988. AIDS and behavioral change to reduce risk: A review. *American Journal of Public Health* 78:394–410.

Brindis, C.D. 1991. *Adolescent Pregnancy Prevention: A Guidebook for Communities.* Palo Alto, Calif.: Health Promotion Resource Center/Stanford Center for Research in Disease Prevention.

Cates, W., and G.S. Bowen. 1989. Education for AIDS prevention: Not our only voluntary weapon. *American Journal of Public Health* 79:871–874.

Centers for Disease Control. 1990. *CDC Plan for Preventing Human Immunodeficiency Virus (HIV) Infection: A Blueprint for the 1990s.* Atlanta, Ga.: U.S. Department of Health and Human Services.

Centers for Disease Control. 1990. HIV-prevalence estimates and AIDS case projections: Results. *Morbidity and Mortality Weekly Report* 39:27–31.

Centers for Disease Control. 1991. *CDC HIV/AIDS Prevention: Special Report on Evaluation.* Atlanta, Ga.: U.S. Department of Health and Human Services.

Centers for Disease Control. 1991. Mortality attributable to HIV infection/AIDS—United States, 1981–1990. *Morbidity and Mortality Weekly Report* 40:41–44.

Coalition for AIDS Prevention and Education, National Organizations Responding to AIDS. No date. *AIDS Primary Prevention Recommendations.* Washington, D.C.: National Organizations Responding to AIDS.

Coates, T.J. 1990. Strategies for modifying sexual behavior for primary and secondary prevention of HIV disease. *Journal of Consulting and Clinical Psychology* 58:57–69.

Coates, T.J., S. Kegeles, R.D. Stall, B. Lo, and S. Morin. 1988. AIDS antibody testing: Will it stop the AIDS epidemic? Will it help persons infected with HIV? *American Psychologist* 43:859–864.

DeJong, W. 1989. Condom promotion: The need for a social marketing program in America's inner cities. *American Journal of Health Promotion* 3:5–16.

Francis, D.P., R.E. Anderson, M.E. Gorman, M. Fenstersheib, and N.S. Padian. 1989. Targeting AIDS prevention and treatment toward HIV-1-infected persons. *Journal of the American Medical Association* 262:2572–2576.

General Accounting Office. 1987. *AIDS Prevention: Views on the Administration's Budget Proposals.* Washington, D.C.: U.S. Government Printing Office.

General Accounting Office. 1990. *AIDS Education: Programs for Out-of-School Youth Slowly Evolving.* Washington, D.C.: U.S. Superindendent of Documents.

General Accounting Office. 1990. *Drug Abuse: Research on Treatment May Not Address Current Needs.* Washington, D.C.: U.S. Government Printing Office.

Guydish, J.R., A. Abramowitz, W. Weeds, D. Black, and J. Sorensen. 1990. Changes in needle sharing behavior among intravenous drug users: San Francisco 1986–88. *American Journal of Public Health* 80:995–997.

Institute of Medicine. 1988. *Confronting AIDS: Update 1988.* Washington, D.C.: National Academy Press.

Institute of Medicine. 1988. *The Future of Public Health.* Washington, D.C.: National Academy Press.

Institute of Medicine. 1991. *HIV Screening of Pregnant Women and Newborns.* Washington, D.C.: National Academy Press.

Kelly, J.A., and J.S. St. Lawrence. 1990. The impact of community-based groups to help persons reduce HIV infection risk behaviors. *AIDS Care* 2:25–36.

Kelly, J.A., and J.S. St. Lawrence. 1990. A skills-training group intervention model to assist persons in reducing risk behaviors for HIV infection. *AIDS Education and Prevention* 2:24–35.

Marin, G. No date. *Culturally Appropriate Interventions in Health Promotion: Why and How.* San Francisco, Calif.: University of San Francisco.

National Organizations Responding to AIDS. 1991. *AIDS Appropriations Recommendations. Fiscal Year 1992.* Washington, D.C.: National Organizations Responding to AIDS.

National Research Council. 1987. *Risking the Future: Adolescent Sexuality, Pregnancy, and Childbearing.* Washington, D.C.: National Academy Press.

National Research Council. 1989. Turner, C.F., H.G. Miller, and L.E. Moses, eds., *AIDS: Sexual Behavior and Intravenous Drug Use.* Washington, D.C.: National Academy Press.

National Research Council. 1990. Miller, H.G., C.F. Turner, and L.E. Moses, eds., *AIDS: The Second Decade.* Washington, D.C.: National Academy Press.

National Research Council. 1991. Coyle, S.L., R.F. Boruch, and C.F. Turner, eds., *Evaluating AIDS Prevention Programs.* Expanded edition. Washington, D.C.: National Academy Press.

Nelkin, D., D.P. Willis, and S.V. Parris, eds. 1990. *A Disease of Society: Cultural Responses to AIDS.* New York: Cambridge University Press.

Office of the Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services. 1990. *Healthy People 2000: National Health Promotion and Disease Prevention Objectives.* Washington, D.C.: U.S. Department of Health and Human Services.

Office of Disease Prevention and Health Promotion, Public Health Service, U.S. Department of Health and Human Services. 1980. *Toward a Healthy Community.* Washington, D.C.: U.S. Department of Health and Human Services.

Office of the Secretary, U.S. Department of Health and Human Services. 1990. *Comprehensive Report on AIDS Expenditures.* Washington, D.C.: U.S. Department of Health and Human Services.

Office of Technology Assessment, U.S. Congress. 1985. *Review of the Public Health Service's Response to AIDS.* Technical Memorandum. Washington, D.C.: Office of Technology Assessment.

Office of Technology Assessment, U.S. Congress. 1988. *AIDS-related Issues: How Effective is AIDS Education?* Staff Paper 3. Washington, D.C.: U.S. Superintendent of Documents.

Panem, S. 1988. *The AIDS Bureaucracy.* Cambridge, Mass.: Harvard University Press.

Peterson, J., and G. Marin. 1988. Issues in the prevention of AIDS among Black and Hispanic men. *American Psychologist* 43:871–877.

Petrow, S., P. Franks, and T.R. Wolfred, eds. 1990. *Ending the HIV Epidemic: Community Strategies in Disease Prevention and Health Promotion.* Santa Cruz, Calif.: ETR Associates/Network Publications.

Presidential Commission on the Human Immunodeficiency Virus Epidemic. 1988. *Report of the Presidential Commission on the Human Immunodeficiency Virus Epidemic.* Washington, D.C.: U.S. Government Printing Office.

Public Health Service, U.S. Department of Health and Human Services. 1987. *Information/Education Plan to Prevent and Control AIDS in the United States.* Washington, D.C.: U.S. Department of Health and Human Services.

Robert Wood Johnson Foundation. 1990. *Proceedings: AIDS Prevention and Services Workshop: February 15–16, Washington, D.C.* Princeton, N.J.: Robert Wood Johnson Foundation Communications Office.

Solomon, M., and W. DeJong. 1986. Recent sexually transmitted disease prevention efforts and their implications for AIDS health education. *Health Education Quarterly* 13:301–316.

Solomon, M., and W. DeJong. 1989. Preventing AIDS and other STDs through condom promotion: A patient education intervention. *American Journal of Public Health* 79:453–458.

Stall, R.D., T.J. Coates, and C. Hoff. 1988. Behavioral risk reduction for HIV infection among gay and bisexual men: A comparison of published results from the United States. *American Psychologist* 43:859–864.

Surgeon General, Centers for Disease Control, Public Health Service, U.S. Department of Health and Human Services. 1988. *Understanding AIDS.* Washington, D.C.: U.S. Government Printing Office.

Surgeon General, Public Health Service, U.S. Department of Health and Human Services. No date. *Surgeon General's Report on Acquired Immune Deficiency Syndrome.* Washington, D.C.: U.S. Department of Health and Human Services.

U.S. Congress. House. 101st Congress, 2nd Session. 1990. Report 101-591. Departments of Labor, Health and Human Services, Education, and Related Agencies. Appropriation Bill, 1991. July 12.

U.S. Congress. House. 101st Congress, 2nd Session. 1990. Report 101-908. Making Appropriations for the Departments of Labor, Health and Human Services, Education, and Related Agencies for the Fiscal Year Ending September 30, 1991, and for Other Purposes. October 20.

U.S. Congress. Senate. 101st Congress, 2nd Session. 1990. Report 101-516. Departments of Labor, Health and Human Services, Education, and Related Agencies. Appropriation Bill, 1991. October 10.

U.S. Government Accounting Office. 1988. *AIDS Education: Reaching Populations at Higher Risk.* Washington, D.C.: U.S. Government Accounting Office.

U.S. Government Accounting Office. 1989. *AIDS Education: Issues Affecting Counseling and Testing Programs.* Washington, D.C.: U.S. Government Accounting Office.

U.S. Government Accounting Office. 1989. *AIDS Education: Staffing and Funding Problems Impair Progress.* Washington, D.C.: U.S. Government Accounting Office.

U.S. Government Accounting Office. 1990. *AIDS Education: Public School Programs Require More Student Information and Teacher Training.* Washington, D.C.: U.S. Government Accounting Office.

Valdiserri, R.O. 1989. *Preventing AIDS: The Design of Effective Programs.* New Brunswick, N.J.: Rutgers University Press.

Watters, J.K., Y.-T. Cheng, M. Segal, J. Lorvick, and P. Case. 1990. Epidemiology and prevention of HIV in heterosexual IV Drug Users in San Francisco, 1986–1989. Presented at the Sixth International Conference on AIDS, San Francisco, Calif., June 20–24.

The White House. 1991. *National Drug Control Consequences: AIDS and the Politics of Public Health.* New Brunswick, N.J.: Rutgers University Press.

Andrew Ziegler

*I feel I am quite fortunate because I know how to access the system. I know all the "right" people. I know how it operates. I know what my rights are. And I know where to go for assistance, because I am a part of the system professionally. But I can tell you it is still never easy. It is particularly difficult when I have to run all over town to see the ophthalmologist, internist, dermatologist, nutritionist, et cetera, and am not feeling well and trying to hold down a full-time job at the same time.*

*But what about the people who don't have the ability to access the system due to social, economic or educational barriers? How do they access a hostile system, a system designed to discourage their use and participation?*

ANDREW ZIEGLER, M.H.S.A.
*September 1990*

## CHAPTER THREE

# CARING FOR PEOPLE WITH HIV DISEASE

Ideally, care for people with HIV disease includes a broad range of health care and social services designed to enhance the quality of life, maximize individual choice, and minimize hospital and institution-based care. Such services should be rendered with compassion in a manner that allows people with HIV disease and their loved ones to act as partners with their caregivers. This chapter recommends ways of moving toward this goal.

HIV disease, especially in its later stages, presents complex challenges for caregivers. The host of opportunistic infections that characterize AIDS may attack virtually any part of the body. HIV disease stubbornly refuses to be limited to any single organ or treatment strategy, since its fundamental mechanism is the pervasive malfunction of the immune system. As long as ten years may pass between infection with the virus and development of full-blown AIDS. Given the great variability in the natural history of HIV, care needs vary greatly over the course of the disease.

Care needs also vary among different populations. HIV disease in women is manifested quite differently than in men; HIV disease in children is manifested quite differently than in adults. Intravenous drug users often suffer from extensive concomitant health problems that are exacerbated by HIV disease. Neurological complications of HIV disease may pose unique challenges. Individuals with HIV disease also have unique social and psychological needs as a result of the dire nature of the illness and the stigma that accompanies diagnosis.

The epidemic is widening most rapidly among poor people in inner cities—a group that historically has had difficulty in gaining access to and finding payment for primary care services. The epidemic also primarily strikes young adults, whereas systems of care for the chronically ill or disabled tend to be tailored to the needs of the elderly. The sheer volume of people who have HIV disease or are at risk of HIV infection in certain hard-hit cities complicates care strategies still further. There are many in the early phases of infection who could benefit from treatments designed to retard the onset of symptoms, as well as benefit from social and mental health services. Unfortunately, many of these people have no point of entry into the health care system. Millions of Americans have no health coverage, and even those people living with HIV disease who have some form of public or private insurance may still face formidable barriers in gaining access to needed care.

## DEVELOPING A CONTINUUM OF CARE

There is a range of services needed by people living with HIV disease and increasing agreement about where and how to provide such services. Ideally what is needed is a continuum of care ranging from minor help for people living at home to congregate living facilities with support services to skilled nursing care for more dependent persons in nursing homes. There is no single model of care that is appropriate for all communities. Nevertheless, in its travels around the country, the Commission discovered a number of elements indispensable for delivering continuous and comprehensive services for people with HIV disease. These include:

- HIV antibody testing that is voluntary and must be accompanied by counseling—both anonymous and confidential testing contribute in different ways and both options should be available;
- education and counseling to help foster and maintain behavioral changes to reduce transmission of the virus;
- medical care, including drug therapy and frequent diagnostic monitoring, ongoing primary care, coordination of inpatient and outpatient care, access to investigational new therapies, and adequate options for long-term care;
- psychological care, including mental health counseling and spiritual support, that is helpful in coping with a frightening and sometimes overwhelming condition;
- drug treatment to help individuals stop using or injecting drugs or adopt safer drug use practices; and
- social services, including a range of housing options and income maintenance, without which medical advances may be beyond the grasp of those who could most benefit from them.

The medical services needed by people living with HIV disease require a multidisciplinary care approach in which a team of health care providers—including primary care physicians and consultants in fields such as infectious diseases, oncology, pulmonary diseases, psychopharmacology, and neurology—works together with patients, their loved ones, and families to develop a plan for care.

A basic goal in developing plans of care for people with HIV disease, as with other illnesses, is to provide dignified and appropriate care in the least restrictive and least institutional setting possible at the lowest possible cost. Cooperation among caregivers is essential in ensuring that a true continuum of care is available, from the time an individual first becomes aware he or she is at risk or learns of HIV seropositivity all the way through the care and support needed in the terminal phases of illness.

Primary care practitioners and medical specialists can provide only some of the services needed by people living with HIV disease. Nurses, psychologists, home health care workers, nutritionists, and other health care and mental health care workers are equally essential in ensuring the availability of a continuum of care. Also crucial are social workers, case managers, patient advocates, and others who help people living with HIV disease find jobs, food, and housing—services that must be available if medical care is to be effective. In some instances, especially where discrimination based on HIV status is involved, people with HIV disease will need legal advice to gain access to basic health and social services and to ensure that their wishes are carried out regarding decisions about terminal care. It is also critical that the patient/provider relationship be based upon mutual respect and cooperation. The patient must feel comfortable that providers are approachable about the full range of care and treatment options. For example, more and more individuals are seeking advice about or are using nontraditional and alternative therapies, usually in conjunction with conventional medical treatments. It is important to establish a relationship in which both the patient and provider are comfortable asking questions.

Throughout its tenure the Commission has heard testimony on local efforts to better coordinate care under the rubric of "case management." The goal of case management is to guide patients efficiently and humanely through the health and social services labyrinths. Case managers serve simultaneously as gatekeepers, advocates, educators, diagnosticians, brokers, and caregivers. They are responsible for far more than coordinating medical care services; they often help find housing, help connect people with specific entitlement programs and other sources of income support and payment for health care, and link people with HIV disease with programs of volunteer support.

A variety of case management styles has emerged to meet the needs of people with HIV disease. Depending upon the model involved, a case manager may be a nurse, a social worker, or a primary care physician. In some instances, case management is funded by government, is hospital based, and is linked primarily to discharge planning. Other case management programs are more community based and follow individuals both in and out of the hospital. In some states case management is provided by

> *Yesterday in our office, a young woman came who had spent an hour and a half on a bus with a temperature of 102, a hematocrit of 25, and a very active six-year-old in tow. She refused hospital admission because she has the sole responsibility of this child, and would not come in until better arrangements could be made. We basically babysat her child and let her sleep in the office until she could regain her strength. This is not an uncommon problem. Women are often subrogating their care to the care of children or, in some cases, other infected spouses.*
>
> MARY YOUNG, M.D.
> *June 1991*

Medicaid programs, this is especially so in those states with home and community-based waiver programs. Yet other programs have emanated from prepaid, managed care programs in health maintenance organizations. The success of a case management program is to a certain extent contingent upon the availability of a spectrum of necessary services.

The Commission believes that case management programs should be supported and further refined to meet the particular needs of people with HIV disease. Case management offers not only the potential for saving costs, limiting hospital stays, and bringing coherence to service delivery, but also may enhance satisfaction and quality of life for those with HIV disease.

### Assuring Availability of Health Care Providers

As the number of people with HIV disease grows, the availability of health care practitioners is an increasing concern. The complexity of care for HIV disease (especially in its later stages) is such that no single medical specialty or discipline encompasses all the necessary skills.

Infectious disease and oncology specialists were initially cast in the role of primary caregivers in the HIV epidemic. However, as the epidemic has progressed, internists, family medicine practitioners, obstetrician/gynecologists, and pediatricians have had to incorporate the care of HIV disease into their general practice. The Commission believes that primary care providers should be able to counsel about HIV transmission risks; diagnose and treat early HIV disease; monitor patient care; and recognize complications later in the disease process that require consultations from specialists or referrals.

Despite the great need for services for people with HIV disease, health care providers have often been reluctant to care for them. The reasons include low reimbursement rates for people whose care is paid for by Medicaid; a lack of familiarity with and understanding of treatment for the disease; fear of becoming infected during the course of treating patients; discomfort in treating gay men or intravenous drug users; and unease in dealing with the psychological stresses of caring for dying young patients with multiple physical and psychological needs.

The Commission believes health care practitioners have an ethical responsibility to provide care to those with HIV disease. Lack of specialized knowledge, concerns about the risk of HIV transmission, increased stress, or disaffection with those who are at risk are not reasons to avoid caring for individuals with HIV disease, although these concerns are real, pervasive, and must be dealt with directly. The following section looks at ways to address these concerns in order to attract, train, and support sufficient numbers of health care providers to meet the challenge of HIV disease.

### Educating Caregivers

HIV education and training programs for health care providers must be improved and expanded, and better methods developed to disseminate state-of-the-art clinical information to the full range of health care providers, including physicians, nurses, physicians' assistants, social workers, psychologists, and other health and mental health care providers. The AIDS Education and Training Centers, federally funded by the Health Resources and Services Administration, have the potential for training thousands of care providers. Education and training programs will require the combined support of government agencies and professional associations. Primary care providers must be trained in HIV care, and specialty backup of technical advice and consultation must be provided. A few states have made continuing medical education in HIV care a condition of relicensure. Some medical professional associations have developed extensive training programs. But they should not be expected to carry the full load.

A greater sense of urgency is necessary in the development and dissemination of professional standards of care for HIV disease. The Agency for Health Care Policy and Research has just begun to develop standards of clinical care for asymptomatic HIV infection. Professional associations of health care workers, with mechanisms in place for reaching their memberships, have a key role to play in standard setting.

Fellowship programs and career development awards for individuals devoted to the care of people with HIV disease are ways of rewarding professionals and helping to establish role models for subsequent trainees. Career development and career advancement for individuals who choose to make AIDS care and education a significant part of their professional life should be available.

The adoption of "universal precautions"—avoidance of exposure to blood and body fluids regardless of whether or not patients or health care workers are believed to be infected—provides the best means of minimizing risks from HIV for both patients and caregivers in the health care setting. Health care workers should be encouraged to adhere vigorously to guidelines for infection control. Concerted efforts must be made to work with health professionals at the earliest stages of training on attitudinal issues and ways to best manage occupational risks. Medical schools, dental schools, nursing schools, and schools of allied health should incorporate into their required curricula training on proper ways to avoid risks from blood-borne pathogens. Such programs must be continued during postgraduate training when young professionals form lifelong habits of practice.

> *Neither dentist would see me, due to HIV infection. One dentist told me that his office was carpeted and he would not be able to sterilize the room after my visit. A second dentist told me she had plants and could not take the risk of my infecting her plants and then infecting her other patients.*
>
> RONALD JERRELL
> *July 1990*

The growing chorus of demands for mandatory, widespread HIV antibody testing of health care workers (HCWs) and patients threatens to drive a wedge between patients and their caregivers. It also misses the point. As the Centers for Disease Control (CDC) has stated,

> Mandatory testing of HCWs for HIV antibody, HBsAg, or HBeAg is not recommended. The current assessment of the risk that infected HCWs will transmit HIV or HBV to patients during exposure-prone procedures does not support the diversion of resources that would be required to implement mandatory testing programs. Compliance by HCWs with recommendations can be increased through education, training, and appropriate confidentiality safeguards.

Mass screening programs would interfere with the doctor-patient relationship, would encourage a false sense of security because of the time between when infection develops and the time when it can be measured by clinical tests, and would imply a significant risk of infection transmission in health care settings when such risk is actually very small, particularly, as CDC has stated, “when HCWs adhere to recommended infection control procedures.”

### WHERE CARE IS PROVIDED

In most cities the care of HIV disease is concentrated in a few hospitals, often in public facilities or teaching hospitals. Many of these hospitals have centralized AIDS care or established AIDS-dedicated units. Hospitals and oupatient care should be linked to community-based services to ensure the continuum of services identified above.

HIV-related services must be expanded to include facilities where underserved populations already receive health care and human services, such as community health centers, migrant health centers, Indian Health Service programs, and the like. In addition, counseling, testing, and care related to HIV disease must be made available in settings where providers speak the language of the communities they serve.

Ongoing research is needed to determine what works best where and how to deliver care to people living with HIV disease. Lessons can be learned from the organization of care for diseases other than HIV. For example, in the context of hemophilia treatment, a system of regional comprehensive treatment centers provides both increased quality and cost-effectiveness by combining sufficient numbers of patients so that economies of scale can justify the single-center multidisciplinary team approach. The AIDS program of the Department of Veterans Affairs, administered by its Veterans Health Administration, has become the largest single source of direct health care services available for treating AIDS patients in the United States. Implementing findings from health services research can help ensure that decisions about where to deliver care are based on individual needs and not administrative convenience or the exigencies of particular reimbursement strategies. Health services research can also help identify the variables that would contribute to a community's decision to centralize care in one unit or hospital. While centralized AIDS care or AIDS-dedicated units may be appropriate for some communities, they may not be practical for others. Evaluating the different approaches as to where and how care can be provided would be very helpful to those communities beginning to organize HIV-related care services.

## Alternatives to hospitalization

Many people with HIV disease would in certain stages of their illness fare better in a less intensive and less expensive setting, but they languish in hospitals because of a lack of access to rental housing, congregate living facilities, nursing homes, and hospices.

Many nursing homes have been reluctant to admit people with HIV disease, citing the fears of other clients, inexperience with managing infectious diseases, and lack of adequate reimbursement. People with HIV disease are typically much younger than most nursing home clients. Moreover, nursing homes may not always meet the needs of people with HIV disease who alternate between periods of illness and relative well-being. The Commission believes that nursing homes must overcome their reluctance to accept people with HIV disease. At the same time, other options for long-term skilled care should be developed and encouraged.

There may also be a poor fit between HIV care needs and traditional hospice services. Hospice clients have traditionally been cancer patients whose prognosis and decline could be predicted with relative certainty. HIV disease is much more unpredictable. People with HIV disease in hospices sometimes wish to seek readmission to a hospital or to undergo therapies (such as ventilator assistance) that would otherwise be unavailable in a traditional hospice setting, where the focus is exclusively on palliative care. In a number of cities, hospices have been created exclusively for people with AIDS. Both options should be available.

*We need the same range of housing options for people living with AIDS as we do for any group of people who may experience deteriorating health: apartments that can accommodate walkers and wheelchairs, congregate living, group homes. And it needs to be subsidized because of our limited incomes. We need home care and personal care attendant services to help people stay in their homes. And we need flexibility so that people can move back and forth between those arrangements as their needs change.*

REBECCA LOMAX, M.S.W., M.P.H.
*July 1990*

People with HIV disease are at the forefront of a trend toward minimizing unnecessary hospitalization by moving treatment to less intensive and more familiar settings. Many procedures formerly requiring hospitalizations, such as lumbar puncture, chemotherapy, and transfusions, are increasingly performed in outpatient settings in the context of HIV care. The ability to receive care outside of the hospital can enhance quality of life, foster autonomy, improve outlook and attitudes, and allow people with HIV disease to spend more time with, and sometimes be cared for by, their loved ones.

The desire of people living with HIV disease to remain at home and be cared for at home has coincided with fiscal pressures to reduce health care costs and shorten the length of hospital stays, fostering the growth of the home health care industry. Scores of companies now offer intravenous, intramuscular, and aerosolized home therapy. AIDS care constitutes a significant portion of this rapidly growing sector of the health care system. Rules and regulations for third-party payment must be adjusted to meet new realities and opportunities for home health care. As home health care efforts grow, increasing attention will be necessary to the quality and cost of such care.

> *There is a real risk of burnout on the part of the physicians and their nursing staffs. . . . We have a major problem as treaters regarding how to take are of our own psyches as well as to maintain the psyches of ur patients and their families. In addition to that, new physicians are not going into AIDS treatment. They are avoiding hemophiliac care. They are avoiding anything that has to do with AIDS care.*
>
> CRAIG KESSLER, M.D.
> *November 1989*

### LINKING HIV PREVENTION WITH PRIMARY CARE

Behavioral change will continue to be the greatest hope for altering the course of the epidemic. Prevention and education programs will continue to be of paramount importance in encouraging such change. Of particular interest in the health care context are programs of HIV antibody testing and counseling. There is a longstanding consensus that HIV antibody testing alone will not suffice in creating and sustaining behavioral change. Nevertheless, when testing is accompanied by supportive pre- and post-test counseling, knowledge of HIV antibody status can help some individuals make the changes necessary to prevent the further spread of HIV.

Beyond its function as an adjunct to behavioral change, HIV antibody testing now has a role to play in the context of early intervention. Discovery that one is HIV positive early in the course of HIV disease can provide hope of a longer life of better quality when diagnosis, monitoring, and treatment begin early in the course of HIV disease. Individuals at risk of HIV infection need ready access to voluntary testing and counseling services in order to find out their HIV status. For many impoverished individuals, gaining entry into a health care and social services system by means of a passport stamped "HIV antibody positive" is a cruel hoax.

Many still experience long delays between the time they test positive and the time they have their first medical evaluation. Too many people with HIV disease first enter the health care system via the hospital emergency room with an episode of *Pneumocystis carinii* pneumonia, a largely preventable illness; too many women first find out they are HIV positive after giving birth to an infected child.

Increasingly, public health providers are being asked to provide primary health care, including the monitoring of health status in the initial stages of HIV disease. HIV antibody testing has expanded from the alternative test sites created in the mid-1980s to a variety of settings, such as: methadone maintenance clinics; sexually transmitted disease clinics; hospital outpatient programs; tuberculosis clinics; family planning centers; and private physicians' offices. HIV antibody testing that is voluntary and accompanied by counseling continues to be essential. Both anonymous and confidential testing contribute in different ways and both options should be available.

It is unrealistic to attempt to rely solely on physicians to provide HIV-related behavioral counseling. Although physicians need more training and experience in taking sexual histories and in dealing with sensitive topics related to drug use or sexual behavior, there also must be greater emphasis on recruiting and training other health and social service professionals to provide the psychological and social support that is necessary to cope with a diagnosis of HIV disease and to make necessary behavioral changes. Although many new HIV testing programs have been put into place, the training of counselors has lagged behind. The Commission believes that HIV education as well as testing services with trained counselors should be available where individuals are likely to seek services. Programs for HIV antibody testing and counseling should be evaluated in part on their record of facilitating referrals and providing ongoing health care interventions.

> *We know that there are too few laboratories in this country to do CD-4 testing and that we don't know what kind of quality we will get in the testing that is done. We know that many hospitals even today do not provide aerosolized pentamidine for their patients, including, I might point out, some of the major academic hospitals in this country. We know that some of those hospitals actually avoid AIDS care altogether. And perhaps most disturbingly, we know that the majority of American physicians do not yet know about these advances and in fact have no access to programs that could teach them about these advances.*
>
> DEBORAH COTTON, M.D., M.P.H.
> *November 1989*

## EXPANDING ACCESS TO INVESTIGATIONAL THERAPIES

Investigational new therapies are a critical aspect of HIV care. A later chapter discusses policy and regulatory questions related to the development of drugs to treat HIV disease, beginning with the proposition that investigational therapies are in many instances the only hope for people with HIV disease. Hence, it is wrong not to offer drugs under study to women, people of color, substance

*The loss of*
*my mother, the loss of my*
*three children, the lack*
*of services have left me with*
*a wish for death. But then I*
*think I want to live.*
*And I want to stop using drugs,*
*but I need someone to care*
*for me. Right now I have*
*known for two years that I am*
*HIV positive. Fortunately,*
*I have not gotten sick.*

YVETTE
*January 1991*

users, prisoners, adolescents, and children—all of whom have experienced difficulty in gaining such access. Frequently individuals enroll in clinical trials because it is their only means of access to primary care. Primary care providers are increasingly being called upon to help people with HIV disease choose among potential investigational therapies and monitor the administration of such drugs.

Information about drugs under study and eligibility requirements for clinical trials must be made widely available for care providers and patients alike. News about the latest results of clinical trials also must be rapidly communicated to health care providers who may not be directly involved in conducting clinical research studies. In some cases, it may be appropriate for federal agencies to conduct widely targeted mailings concerning breakthroughs in HIV care to supplement information available in medical journals and through professional associations. Access to a growing number of therapies is also currently available through the parallel track or expanded access programs administered by pharmaceutical companies. This can make medications available to a great many individuals for whom there are no alternatives. However, the process of gathering data to monitor patients' reactions to drugs under study is extremely time-consuming and may differ from drug to drug (even though individual patients may need a number of such drugs over the course of their illness). The time and paperwork involved is daunting for individual care providers who lack the resources of clinical investigators. Some of these problems could be obviated by the development of uniform guidelines for data collection for drugs dispensed in expanded access programs, including data for individuals simultaneously taking multiple investigational drugs. Ways must be found to assist health care providers in the administration of such efforts.

### [illegible]

The percentage of AIDS cases related to injection drug use has increased sharply, from 18 percent before 1985 to nearly 33 percent in 1990–1991. There are an estimated 500,000 to 1.5 million injection drug users in the United States, and only 15 to 20 percent are estimated to be receiving treatment for their drug dependency. Drugs other than injected ones, particularly alcohol and crack cocaine, are also strongly implicated in increased risk of HIV infection because of the role they play in impairing judgment about sexual risk taking.

Health care workers in primary care roles must be able to recognize substance use problems and provide care in a compassionate and nondiscriminatory manner. Substance users have often been "unwelcome guests" in the health care system and may have problems attaining care. Providers fear that they may leave the hospital against medical advice and may seek or use drugs while hospitalized. Intravenous drug users often have no private insurance or even public medical assistance. In addition, medical problems related to their substance use may be difficult to treat, e.g., collapsed veins, cirrhosis, or other liver diseases. The failure to obtain compassionate and needed care may in turn foster negative attitudes among substance users about the health care system, which in turn may result in a reluctance on the part of substance users to seek care in the future.

Attention to how to care for drug users and deal with substance use issues has been a major gap in both medical and nursing education. Physicians should be able to take a drug use history and to understand the care needs of substance users. Primary care providers do not necessarily have to become chemical dependency treatment experts, but they should be familiar with treatment options and know how to make appropriate diagnoses and referrals. Most drug treatment, including methadone maintenance, detoxification, twelve-step programs, and therapeutic communities, takes place outside of traditional health care settings. The AIDS epidemic underscores the importance of integrating such services with primary care. Such integration should be a top priority.

he percentage
of AIDS cases
related to injection
drug use has
increased sharply,
from 18 percent
before 1985 to
nearly 33 percent
in 1990–1991.

## [illegible]

One of the most remarkable features of the HIV epidemic has been the extent to which services needed by people living with HIV disease have been provided by volunteers. Many people with HIV disease need assistance in activities of daily living—help with cooking, cleaning, and other household chores and with transportation to appointments. At times the assistance involves helping with the administration of medications or providing medical services that can be accomplished by lay people with minimal training. These services are either provided informally or through community-based organizations that utilize volunteer services. Much unpaid work on behalf of people living with AIDS is not thought of as "volunteering," because it happens in the context of kinship relationships.

Volunteer labor is not equally available in all regions of the country or to all people. As the epidemic continues, the supply of volunteers may prove inadequate. It may prove more difficult to enlist volunteers on behalf of people who use drugs or to find peo-

*I polled a bunch of volunteer managers at other agencies and said, "Here's your chance to say something. What would you want me to pass on for you?" And one man just sighed on the phone, this man at the San Francisco AIDS Foundation, and he said, "Just tell them that without the huge volunteer work force in our organizations this epidemic would have crippled the country a long time ago. Just make sure they know that."*

LAURIE SHERMAN
*July 1990*

ple who can afford to volunteer in communities ravaged by poverty. The gay community is losing many volunteers to burnout and to sickness and death, and others are choosing to funnel their energies into spurring governmental action to provide needed services.

Community-based organizations are struggling to keep pace with increased caseloads. Many such groups are finding that the skills and energies necessary to get them off the ground are different from those needed to sustain them. Many community-based organizations are struggling to diversify and solidify sources of funding, as they run out of funds from sources of seed money and demonstration grants.

Federal, state, and local entities must provide support for training, technical assistance, supervisory staff, and program coordination to acknowledge and support the community-based organizations, family members, friends, and volunteers who are an integral part of the HIV care system. Applications for funding are frequently too complex and bureaucratic requirements too burdensome to allow programs to flourish in communities of greatest need. Community-based organizations must be given greater lattitude to experiment with programs to address the needs of particular communities.

Small investments of funds in supporting and training volunteers will yield enormous returns of invaluable services. Funders should support newer programs while resisting the temptation to pay for such support by trimming viable existing programs. Community-based organizations formed in communities of color and in cities where there are large numbers of intravenous drug users with HIV disease have special needs. Inadequate and unstable funding sources contribute to unnecessary competition among local groups, when coalition building is essential.

In the second decade of the AIDS epidemic, care will have to be provided to many thousands of people. It will have to include social and mental health services alongside medical care. It will require trained providers at locations across the country where people come for care. And it will require the commitment of the nation to make care accessible and affordable.

# RECOMMENDATIONS

1. Government should assure access to a system of health care for all people with HIV disease.

   At a minimum, a system of care for all people with HIV disease should include a package of continuous and comprehensive medical and social services designed to enhance quality of life and minimize hospital-based care. States, counties, and municipalities should assure that such services are available for individuals with HIV disease. Case management programs should be available to coordinate such care. These services must include:

   - HIV antibody testing that is voluntary and must be accompanied by counseling—both anonymous and confidential testing contribute in different ways and both options should be available;
   - education and counseling to help foster and maintain behavioral changes to reduce transmission of the virus;
   - medical care, including drug therapy and frequent diagnostic monitoring, ongoing primary care, coordination of inpatient and outpatient care, access to investigational new therapies, and adequate options for long-term care;
   - psychological care, including mental health counseling and spiritual support, that is helpful in coping with a frightening and sometimes overwhelming condition;
   - drug treatment to help individuals stop using or injecting drugs or adopt safer drug use practices; and
   - social services, including a range of housing options and income maintenance, without which medical advances may be beyond the grasp of those who could most benefit from them.

2. HIV-related services should be expanded to facilities where underserved populations receive health care and human services, in part to ensure their increased participation in trials of investigational new therapies.

3. HIV education and training programs for health care providers should be improved and expanded, and better methods should be developed to disseminate state-of-the-art clinical information about HIV disease, as well as drug and alcohol use, to the full range of health care providers.

   The Commission believes all health care providers have an ethical responsibility to care for people with HIV disease. In order to equip providers to better counsel and care for people with HIV disease, government at all levels and local agencies and institutions must develop more effective education programs and methods for getting the information to all providers, particularly primary care providers.

Programs to train health care providers to recognize and manage drug and alcohol use must be expanded, and programs that integrate treatment of drug use with primary care must be created and supported. The Commission believes more federal funds are needed for these efforts.

4. **Federal, state, and local entities should provide support for training, technical assistance, supervisory staff, and program coordination to acknowledge and support the family members, friends, and volunteers who are an integral part of the care system of a person with HIV disease.**

## SELECTED BIBLIOGRAPHY

American Medical Association, Council on Ethical and Judicial Affairs. 1987. Ethical issues involved in the growing AIDS crisis. *Journal of the American Medical Association* 259:1360–1361.

Andrulis, D.P. 1989. *Crisis at the Front Line: The Effects of AIDS on Public Hospitals.* New York: Twentieth Century Fund.

Arno, P.S. 1986. The non-profit sector's response to the AIDS epidemic: Community-based services in San Francisco. *American Journal of Public Health* 76:1325–1330.

Arno, P.S., D. Shenson, N.F. Siegel, P. Franks, and P.R. Lee. 1989. Economic and policy implications of early intervention in HIV disease. *Journal of the American Medical Association* 262:1493–1498.

Arnow, P.M., L.A. Pottenger, C.B. Stocking, M. Siegler, and H.W. DeLeeuw. 1989. Orthopedic surgeons' attitudes and practices concerning treatment of patients with HIV infection. *Public Health Reports* 104:121–129.

Arras, J.D. 1988. The fragile web of responsibility: AIDS and the duty to treat. *Hastings Center Report* 18(2):10–20.

Association of American Medical Colleges, Committee on AIDS and the Academic Medical Center. 1989. *The HIV Epidemic and Medical Education.* New York: American Association of Medical Colleges.

Barnes, M., N.A. Rango, G.R. Burke, and L. Chiarello. 1991. The HIV-infected health care professional: Employment policies and public health. *Law, Medicine & Health Care* 18:311–330.

Bartlett, J.G. 1988. Who will take care of patients with AIDS? *Washington Post.* Health supplement. April 5:10–11.

Becker, C.E., J.E. Cone, and J. Gerberding. 1989. Occupational infection with human immunodeficiency virus. *Annals of Internal Medicine* 110:653–656.

Benjamin, A.E. 1988. Long-term care and AIDS: Perspectives from experience with the elderly. *Milbank Quarterly* 66:415–443.

Bennett, C.L., J.B. Garfinkle, S. Greenfield, D. Draper, and W. Rogers. 1989. The relation between hospital experience and in-hospital mortality for patients with AIDS-related PCP. *Journal of the American Medical Association* 261:2975–2979.

Bosk, C.L., and J.E. Frader. 1990. AIDS and its impact on medical work: The culture and politics of the shop floor. *Milbank Quarterly* 68(Suppl. 2):257–279.

Brennan, T.A. 1987. The acquired immunodeficiency syndrome (AIDS) as an occupational disease. *Annals of Internal Medicine* 107:581–583.

Centers for Disease Control. 1991. Recommendations for preventing transmission of human immunodeficiency virus and hepatitis B virus to patients during exposure-prone invasive procedures. *Morbidity and Mortality Weekly Report* 40.

Cooke, M., and M.A. Sande. 1989. The HIV epidemic and training in internal medicine: Challenges and recommendations. *New England Journal of Medicine* 321:1334–1338.

Cotton, D.J. 1988. The impact of AIDS on the medical care system. *Journal of the American Medical Association* 260:519–523.

Cotton, D.J. 1989. Improving survival in acquired immunodeficiency syndrome: Is experience everything? *Journal of the American Medical Association* 261:3016–3017.

Currey, C.J., M. Johnson, and B. Ogden. 1990. Willingness of health-professions students to treat patients with AIDS. *Academic Medicine* 65:472–474.

Daniels, N. 1991. Duty to treat or right to refuse? *Hastings Center Report* 21:36–46.

Doebbeling, B.N., and R.P. Wenzel. 1990. The direct costs of universal precautions in a teaching hospital. *Journal of the American Medical Association* 264:2038–2087.

Finck, B.K., M.H. Katz, and S.R. Hernandez. 1989. The care of asymptomatic HIV-infected patients. *Western Journal of Medicine* 151:464–466.

Fox, R.C., L.H. Aiken, and C.M. Messikomer. 1990. The culture of caring: AIDS and the nursing profession. *The Milbank Quarterly* 68(Suppl. 2):226–256.

Freedman, B. 1989. Health professions, codes, and the right to refuse to treat HIV-infectious patients. *Hastings Center Report* 18:20–25.

Gellin, B.G., and D.E. Rogers. 1991. Branding doctors with HIV. *New York Times.* January 2:A13.

Gerberding, J.L., and W.P. Schecter. 1991. Surgery and AIDS: Reducing the risk. *Journal of American Medical Association* 265:1572–1573.

Gerbert, B., B.T. Maguire, and T.J. Coates. 1990. Are patients talking to their physicians about AIDS? *American Journal of Public Health* 80:467–469.

Gerbert, B., B.T. Maguire, S.B. Hulley, and T.J. Coates. 1989. Physicians and acquired immunodeficiency syndrome: What patients think about human immunodeficiency virus in medical practice. *Journal of the American Medical Association* 262:1969–1972.

Gostin, L. 1989. HIV-infected physicians and the practice of seriously invasive procedures. *Hastings Center Report* 19(1):32–39.

Gostin, L. 1989. Hospitals, health care professionals, and AIDS: The "right to know" the health status of professionals and patients. *Maryland Law Review* 48:12–54.

Gostin, L.O., ed. 1990. *AIDS and the Health Care System.* New Haven, Conn.: Yale University Press.

Green, J., and P.S. Arno. 1990. The "Medicaidization" of AIDS: Trends in the financing of HIV-related medical care. *Journal of the American Medical Association* 264:1261–1266.

Hauptman, P.J., and M.B. Feinberg. 1990. Occupational exposure to HIV among house staff. *New England Journal of Medicine* 323:1356.

Hayward, R.A., and M.F. Shapiro. 1991. A national study of AIDS and residency training: Experiences, concerns, and consequences. *Annals of Internal Medicine* 114:23–32.

Henderson, D.K. 1990. HIV-1 in the health care setting. In G.F. Mandell, R.G. Gordon, Jr., and J.E. Bennett, eds., *Principles and Practices of Infectious Diseases.* 3rd edition. New York: John Wiley.

Henderson, D.K., B.J. Fahey, M. Willy, J.M. Schmitt, and K. Carey. 1990. Risk for occupational transmission of human immunodeficiency virus type 1 (HIV-1) associated with clinical exposures: A prospective evaluation. *Annals of Internal Medicine* 113:740–746.

Imperato, P.J., J.G. Feldman, K. Nayeri, and J.A. DeHovitz. 1988. Medical students' attitudes towards caring for patients with AIDS in a high incidence area. *New York State Journal of Medicine* 88:223–228.

Jacobson, P.D., P.A. Lindsey, and A.H. Pascal. 1989. *AIDS-Specific Home and Community-Based Waivers for the Medicaid Population.* Santa Monica, Calif.: RAND Corporation.

Jellinek, P.S. 1988. Case managing AIDS. *Issues in Science and Technology* 4:59–63.

Jonsen, A.R. 1990. The duty to treat patients with AIDS and HIV infection. In L.O. Gostin, ed., *AIDS and the Health Care System.* New Haven, Conn.: Yale University Press.

Kerr, P. 1991. Medical society urges that all New Jersey hospital patients be tested for AIDS. *New York Times.* May 2:A11.

Lambert, B. 1989. Flaws in the health care system emerge as epidemic rages. *New York Times.* February 8:A1.

Lambert, B. 1990. AIDS war shunned by many doctors: Patients are said to miss out on life-prolonging drugs. *New York Times.* April 23:A1.

Levine, C. 1990. In and out of the hospital. In L.O. Gostin, ed., *AIDS and the Health Care System.* New Haven, Conn.: Yale University Press.

Lewis, C.E., and K. Montgomery. 1990. The HIV-testing policies of U.S. hospitals. *Journal of the American Medical Association* 264:2764–2767.

Makadon, H.J. 1991. Assessing HIV infection in primary care practice. *Journal of General Internal Medicine* 6(Suppl. 1):S2–S7.

Makadon, H.J., S.F. Delbanco, and T.L. Delbanco. 1990. Caring for people with AIDS and HIV infection in hospital-based primary care practice. *Journal of General Internal Medicine* 5:446–450.

Northfelt, D.W., R.A. Hayward, and M.F. Shapiro. 1988. The acquired immunodeficiency syndrome is a primary care disease. *Annals of Internal Medicine* 109:773–775.

Nunn, P., D. Kibuga, A. Elliott, and S. Gathua. 1990. Impact of human immunodefiency virus on transmission and severity of tuberculosis. *Transactions of the Royal Society of Tropical Medicine and Hygiene* 84(Suppl. 1):9–13.

Oleske, J.M. 1989. Who cares for the human immunodeficiency virus-infected child? *Pediatrics* 84:727.

Peterson, L.M. 1989. AIDS: The ethical dilemma for surgeons. *Law, Medicine, and Health Care* 17:139–144.

Rogers, D.E., and E. Ginzberg, eds. 1989. *Public and Professional Attitudes Toward AIDS Patients: A National Dilemma.* Boulder, Colo.: Westview Press.

Rosenthal, E. 1990. Practice of medicine is changing under specter of the AIDS virus. *New York Times.* November 11:A1.

Rothman, D.J., E.A. Tynan, and the New York City Task Force on Single-Disease Hospitals. 1990. Advantages and disadvantages of special hospitals for patients with HIV infection: A report by the New York City Task Force on Single-Disease Hospitals. *New England Journal of Medicine* 323:764–768.

Smith, M.D. 1990. An integrated primary care system for HIV disease. *Maryland Medical Journal* 39:173–176.

Smith, M.D. 1991. Primary care and HIV disease. *Journal of General Internal Medicine* 6(Suppl. 1):S56–S62.

Steinbrook, R., B. Lo, J. Tirpack, J.W. Dilley, and P.A. Volberding. 1985. Ethical dilemmas of caring for patients with AIDS. *Annals of Internal Medicine* 103:787–790.

Turner, B. 1990. Models of ambulatory care: Opportunities for SGIM. *SGIM (Society for General Internal Medicine) News* 13:2,4–5.

Volberding, P. 1989. Supporting the health care team in caring for patients with AIDS. *Journal of the American Medical Association* 261:747–748.

Wong, E.S., J.L. Stotka, V.M. Chinchilli, S. Williams, and C.G. Stuart. 1991. Are universal precautions effective in reducing the number of occupational exposures among health care workers? A prospective study of physicians on a medical service. *Journal of the American Medical Association* 265:1123–1128.

Wofsy, C. 1988. AIDS care: Providing care for the HIV infected. *Journal of Acquired Immune Deficiency Syndromes* 1:274–283.

Zuger, A., and S.H. Miles. 1987. Physicians, AIDS and occupational risk: Historic traditions and ethical obligations. *Journal of the American Medical Association* 258:1924–1928.

Kathryn Anastos MD

*We can't go any longer in trying to provide care without addressing the underlying failures of our health care system. It's a national shame that we do not guarantee health care to all of our people. We are struggling now against enormous odds, both for the acute care needs of people with HIV infection as well as the long-term needs of people with HIV infection. We're not going to improve longevity if people can't get into care.*

*We need to improve our education efforts. I cannot believe that we have not put more resources into education at the community level so that both women and men will recognize that they are at some risk for HIV infection and can make some kind of informed choice about whether to access health care, if it exists, in their community.*

KATHRYN ANASTOS, M.D.
*June 1991*

## CHAPTER FOUR

# HEALTH CARE FINANCING

Gaps in the United States health care financing system have been made increasingly evident by the HIV epidemic. Millions of Americans are without health insurance and thus face significant barriers to needed care. The first decade of AIDS coincided with a period of great ferment in health care financing, during which numerous proposals emerged for improving access and quality of care and limiting rising costs. Although health care access is not a problem unique to people with HIV disease, the HIV epidemic does pose some unique challenges for the health care system. It adds to a problem that has grown beyond the scale that can be solved by piecemeal tinkering. Fundamental reforms are needed, and it will clearly require political courage to propose and implement them.

Part of the Commission's mandate from Congress is to "evaluate the adequacy of, and make recommendations regarding, the financing of health care . . . relating to AIDS." This chapter does so in considerable detail. By necessity, however, the discussion goes beyond the mandate, for a financing reform proposal addressed solely to HIV disease would provide selectively and perhaps only temporarily for that population while ignoring the larger, more systemic problem.

The Commission urges the President and Congress to address the health care problems of *all* people living in the United States by supporting universal health care coverage. This coverage should be comprehensive and include prescription drugs. No person living in the United States should be denied health care because of an inability to pay, nor should people be forced into poverty or left without dignity because they are unfortunate enough to have a major health problem. Our nation must do what virtually every other major industrialized nation has done—adopt a universal health plan that ensures access to health care for all its citizens.

Unless action is taken, the ranks of the uninsured and underinsured will continue to grow, opportunities for HIV education, prevention, counseling, and early intervention will continue to be missed, and individuals whose HIV disease requires acute care will turn increasingly to the already overburdened public hospital system.[*]

## THE PARTICULAR CHALLENGES OF HIV DISEASE

Original estimates of the costs of caring for people with AIDS were quite high. The first and most widely cited estimate, made in the mid-1980s, was $147,000 for each patient for the direct medical costs of AIDS care from AIDS diagnosis to death. This figure has been revised substantially downward in several subsequent studies, as ambulatory care has supplanted expensive hospitalizations and as costs for many of the drugs needed to treat manifestations of AIDS have declined. Although caring for people with HIV disease is still quite expensive, in the aggregate, costs for HIV care presently and in the foreseeable future probably total no more than 2 percent of total U.S. health expenditures. In this context, therefore, it is probably more accurate to think of HIV disease as posing "financing," rather than "cost" problems.

The financing problems are severe. They arise in part because much of the need for HIV care is concentrated in particular cities and among people whose care is not covered by private insurers. Moreover, both private and public third-party payers often fail to cover the full range of services needed.

Exclusion from private coverage has resulted from a combination of factors such as the clinical nature of HIV disease, the demographic characteristics of people with AIDS, and the employer-centered nature of health insurance. HIV disease is disproportionately represented among the poor and people of color, who are at greater risk of being uninsured. Even those with HIV disease who have private health insurance often find coverage wanting. Employment-based private health insurance frequently fails to provide comprehensive coverage of preventive care, outpatient care, long-term care, and prescription drugs, all of which are key elements of care for HIV disease.

A substantial portion of the costs of caring for people with HIV disease is being shifted from private insurers to public-sector programs. State, county, and municipal governments are experiencing enormous financial and political difficulties as they are pressed into service as providers of last resort in rendering uncompensated care. Those who are impoverished by the disease and "spend down" to meet eligibility for public programs will find that Medicaid coverage varies widely from state to state, often leaving people with HIV disease without effective entitle-

---

[*] Material in this chapter is drawn from a technical report prepared for the National Commission on AIDS (Davis et al., 1991). All cost estimates and projected savings cited in this chapter are based on information submitted by consultants from The Johns Hopkins University School of Hygiene and Public Health and The Actuarial Research Corporation to the National Commission on AIDS. Further information regarding these calculations is available from the Commission.

ment to care. For example, some states did not cover the cost of AZT under their Medicaid program even after the drug became licensed. Now all states cover AZT, but in some cases it took well over a year before the only available treatment for people with AIDS was covered under Medicaid.

### THE SCOPE OF THE PROBLEM

It is currently estimated that at least one million individuals in the United States are HIV infected. The Centers for Disease Control (CDC) estimated that in 1990 there were between 111,000 and 122,000 people with AIDS living in the United States, and the projection for 1993 is between 151,000 and 225,000 people. These alarming figures necessitate immediate action. The primary recommendation of the Commission is that universal health care coverage should be provided for all persons living in the United States. However, in the interim, the Commission recommends a series of immediate short-term steps to address the urgent problem of inadequate coverage for people with HIV disease. These steps should build on existing programs such as Medicare, Medicaid, and the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, which already provides limited assistance. Such steps are well within the nation's economic and administrative capability and should be a top priority for policy attention.

Similarly, the Commission encourages long-term reform of the private health insurance industry. However, in this report the Commission has focused primarily on recommendations that can result in immediate changes in publicly funded programs. These changes will provide prompt assistance to those who are poor and seriously disabled and who are therefore in most urgent need.

This chapter provides a summary of the current health care financing system and highlights gaps in health care financing as experienced by individuals with HIV disease. The recommendations in this report are set forth with the objective of extending current health care financing coverage to more people and improving the benefits provided. In view of the charge to this Commission, our recommendations apply specifically to people living with HIV disease, but they could reasonably be implemented incrementally for all people with serious chronic illnesses requiring expensive, recurring care.

> *I'd like just to make one comment and that's my late realization in my career that health care is not a constitutional right. Health care is a business, and that's why we don't have access to health care for everyone.*
>
> CARMEN ZORILLA, M.D.
> *June 1991*

### CURRENT ESTIMATES OF THE COST OF CARING FOR A PERSON WITH HIV DISEASE

There have been a number of efforts to delineate the costs of caring for people with AIDS. Most such studies have reviewed costs and charges for cohorts of gay male patients from the time of an initial AIDS diagnosis until death. The most recent and realistic estimate of the annual direct medical care cost for treating an individual with AIDS is $32,000 in 1990 (Hellinger, 1991).[*] However, because the proportion of intravenous drug users in the AIDS patient population is rising, this estimate may have to be adjusted upward in the future. Intravenous drug users with HIV disease tend to incur higher than average annual costs than gay men with HIV disease as a result of their generally poorer state of health and inability to obtain outpatient and preventive care. Future cost estimates will also have to be adjusted to reflect changing treatment modalities, but the direction of change could be either up or down. New drugs may be more or less costly, depending on their cost of manufacture, their effectiveness, and the manner in which they are administered. Even if more costly, better drugs may still lead to fewer hospitalizations and shorter lengths of stay. There may well be other cost factors to be considered, particularly in rural settings where the cost of transportation is a factor and where already tenuous resources for general health care may be disastrously affected by the unexpected expense of AIDS care.

Much of the estimated cost of care for AIDS and for earlier stages of HIV disease, especially early intervention care, reflects high drug prices. Medications are key to improvements in the functional status of patients and to the prevention of *Pneumocystis carinii* pneumonia, a leading cause of hospitalization and death for people with HIV disease. The average cost of providing early intervention to individuals with HIV disease was recently estimated to be $5,904 per year in 1990 (Arno and Shenson, 1990). This cost is somewhat lower than in earlier years, but it still poses a considerable financial burden to those who have moderate or low incomes or are uninsured. It may even be a burden for insured people, as prescription drugs are not covered by all private insurers, nor does Medicare cover them. Even with Medicaid, coverage of drugs is selective and varies from state to state.

## THE CURRENT SYSTEM

The United States provides health care through a patchwork system centered on employer-sponsored private health insurance. This is supplemented, at least in part, by government entitlement programs, most notably Medicare and Medicaid, covering primarily the elderly, the disabled, and the poor. Recent estimates indicate that private health insurance covers approximately 29 percent of individuals with AIDS, Medicaid covers approximately 40 percent, Medicare covers 2 percent, and the remaining 29 percent are uninsured. Some of the uninsured individuals may be eligible for direct

---

[*] Of course, direct medical care costs are not the only costs of AIDS. As noted by Yelin and colleagues in 1991: "... the largest component of cost of human immunodeficiency virus (HIV)-related illness is due to lost work rather than to direct expenditures for medical care, reflecting the onset of this condition among persons in the first half of their careers. ..." Other indirect costs of HIV disease include prevention and education programs, screening of the blood and tissue supply, and training of health care workers.

care from such sources as the Department of Veterans Affairs, prisons, public hospitals, or other programs.

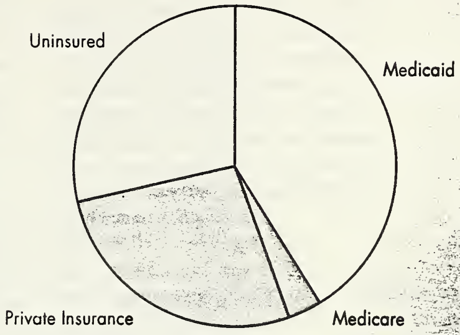
### Private Insurance

As it is currently structured, private health insurance is not well suited to respond to HIV disease because of limitations in the range of services covered and the eligibility for coverage. The vast majority of individuals with private health insurance secure such coverage through their workplace or that of a spouse or parent. When health insurance is secured through large employer-sponsored group plans, there are few initial restrictions on obtaining coverage.

Federal law requires employers with 20 or more employees to permit continued coverage for a period of time following termination of employment if the insured are able to pay the full premium and additional costs. Health plans for fewer than 20 employees are likely to exclude people with AIDS or HIV infection or charge higher premiums. Eight states and the District of Columbia have taken steps to implement premium-paying programs for individuals with chronic health conditions who are unable to continue paying their private individual or group insurance premiums. The Commission believes that all states and/or the federal government should adopt some form of premium-paying policy.

Even good faith employers, fully committed to keeping people with HIV disease on their payroll and covered by employer-based insurance, find it difficult to do so. When just one person is diagnosed with HIV disease on an employer-based insurance program, insurance premiums are often raised. For many employers, such a raise in insurance premiums can make the insurance plan virtually unaffordable. The cost of insurance could, in fact, force an employer to reduce or eliminate the health insurance program. In some cases, it may force an employer out of business. This is particularly true for small employers who may have a number of employees who need HIV-related services. The significant increase in premiums that can result when an insurance company discovers that one or more employees need HIV-related services must be addressed.

INSURANCE COVERAGE OF INDIVIDUALS WITH AIDS, 1990



Source: Davis/ et al., 1991.

The linking of health insurance to employment is problematic for people living with HIV disease. People with HIV disease may become too debilitated to work. Even when they are able to work on a reduced schedule, employers may not be willing to accommodate their needs for time off to cope with intercurrent illnesses or to keep various medical appointments. In addition, many with HIV disease have faced discrimination in the workplace. They have been fired or laid off because of their HIV status, without regard to their ability to continue working. One study of work loss among individuals with HIV disease found that in a sample of 193 individuals, 50 percent who worked prior to the onset of symptoms stopped working within two years. The authors noted that improved treatments would help slow the rate of work loss (Yelin et al., 1991).

> *The problem is that insurance companies single out these men because they do not want the financial burden of taking care of what they have entered into a contract to provide. Insurance companies cut back on ways of providing health care of these individuals afflicted with HIV by cutting back on enefits which keep them alive. This is a terrible disgrace. They make insurance premiums rise astronomically, forcing people with limited incomes, even with employment, to drop their insurance and then receive benefits as near as they are from the public sector.*
>
> PAUL ROTHMAN, M.D.
> *January 1990*

Individually purchased health insurance is not commonly held by people with HIV disease because most insurance companies screen out people who are already HIV infected and even those believed to be at risk.

There are other problems with private insurance, even when it is available. For instance, the range of health care benefits provided under private insurance varies considerably and may not include coverage for costly prescription drugs. In rare instances, insurers or self-insured groups have attempted to impose restrictive caps on payments for AIDS-related treatments, caps that have not been used for any other life-threatening diseases.

Another fundamental limitation of private insurance that is particularly relevant for people with HIV disease is the traditional restrictions on coverage of experimental drugs and procedures. Treatments that are technically experimental may be the standard of care for HIV disease. To exclude coverage of experimental treatments may be to exclude the sole choice available to someone with HIV disease.

### Medicaid

Medicaid is currently the most important source of financing for AIDS and HIV-related health care benefits (HCFA, 1990). Forty percent of people with AIDS are covered by Medicaid, and ninety percent of children with AIDS are covered by Medicaid. Recent studies reveal a strong trend that has been dubbed the "Medicaidization" of AIDS, that is, a shift in the distribution of individuals with third-party financing from private insurance to Medicaid (Green and Arno, 1990; Merlis, 1990). It is unclear whether this can be explained better by the increase in the number of low-income individuals contracting the disease or by the reduction in coverage of the disease by private insurance; probably both factors contribute to this dramatic trend.

Evidence of such "Medicaidization" is abundant. Whereas Medicaid pays for approximately 11 percent of total health care costs in the United States, it funds approximately 25 percent of AIDS care. There is an unfortunate side to this trend, for although Medicaid is designed to cover low-income people, it falls short of serving the needs of many poor individuals because of the stringent criteria defining "low-income" and the prerequisite that assets be below a certain minimum. In addition to poverty restrictions, an individual must meet one of the categorical eligibility criteria by being over 65, a member of a family with dependent children, or totally disabled. For most people with HIV disease, eligibility for Medicaid is through disability, which requires a clinical diagnosis of AIDS. As a result, Medicaid is generally available only to very poor individuals and during the later stages of HIV disease.

Eligibility criteria and types of benefits covered vary considerably from state to state, and coverage is almost nonexistent in the Commonwealth of Puerto Rico and the U.S. territories. While some states provide coverage for the complete range of benefits needed, others provide a more restricted range of benefits including only partial and selective coverage of costly prescription drugs. The low provider-payment rates under Medicaid raise other concerns, specifically the reluctance of physicians to serve Medicaid patients and the financial burden placed on hospitals serving Medicaid patients. Green and Arno found that "physicians are reimbursed by Medicaid an average of 33 percent of the rates paid by private insurance in San Francisco and 15 percent in New York. In New York, an intermediate care office visit is compensated at $84 by private insurance compared with $11 by Medicaid." They also found a "disproportionate number of hospitalizations of AIDS patients with Medicaid beginning in an emergency room, unmediated by a physician responsible for continuing care." Clearly, this situation does not serve anyone well. Patients are poorly served because of late intervention and limited services. The health care system is poorly served because of high overhead costs and the use of expensive inpatient services when early intervention might have prevented the need for them.

### Medicare

Medicare provides coverage for approximately 2 percent of people with AIDS (HCFA, 1990). This is largely as a result of the limiting effect of eligibility criteria. Before qualifying for Medicare, individuals who are not elderly must qualify for Social Security Disability Insurance (SSDI). Before obtaining Medicare they must wait five months from diagnosis of a disabling condition to receive SSDI payments and then survive a two-year waiting period—a total of 29 months. It is also important to note that eligi-

*The sobering reality is that health care is indeed rationed in this country. Only the rich can afford it. Only the employed can attain it. Only the educated can exploit it. And those who need it are left without it. Subsequently, they die faster. We have put a price on living longer.*

WILLIAM WAYBOURN
*July 1990*

bility for Medicare requires a history of employment. The Commission believes SSDI beneficiaries who are disabled and have HIV disease or another serious chronic health condition should have the option of purchasing Medicare during the current two-year waiting period.

Also, while there are obstacles to becoming eligible for Medicare, there are also drawbacks to Medicare coverage once one receives it. The lack of prescription drug benefits and limited long-term care benefits poses real problems for people with HIV disease. Out-of-pocket costs can be prohibitive for a beneficiary as a result of limitations such as deductibles, coinsurance, the Part B premium for physician services, and uncovered services.

### ADDITIONAL PROBLEMS OF ACCESS TO CARE

A variety of factors may cause delays or serve as barriers to early treatment and care of individuals with HIV disease. Some of these factors are highlighted in the preceding chapter, which discusses limitations in the organization and delivery of HIV care. The preceding chapter also looks at ways in which fear of HIV transmission in the health care setting imperils access to care by driving a wedge between patients and their caregivers. The following section discusses some additional barriers to HIV care that relate to financing issues.

### PREVENTION AND EARLY INTERVENTION

CDC estimates that approximately 60 percent of individuals with HIV infection could benefit from early intervention. This means that even if there were no further spread of the virus, 480,000 to 720,000 people should receive such care right now. However, individuals such as intravenous drug users, the homeless, and those who live in rural areas and who lack access to care in general, may have limited or no access to counseling and testing and diagnostic resources and may not receive care until it is an emergency. Many others who do not have a primary care provider do not have access to appropriate testing and counseling services and have no access to the early intervention services they may have been told are now available for people with HIV disease. Others are afraid to be tested for a variety of reasons, not the least of which is the very real fear that they will be discriminated against if they test positive, perhaps losing their health insurance. CDC estimates that only 12 percent of people who are infected know of their HIV serostatus, and fewer than that are receiving treatment. Equally alarming, when counseling is unavailable or inadequate, HIV-infected individuals do not have sufficient information upon which to base decisions regarding treatment and risk behavior changes.

### DRUG TREATMENTS

It has been estimated that 90 percent of the early intervention costs for HIV infection are for prescription drugs, principally AZT and aerosolized pentamidine (Arno, 1990). CDC estimates that approximately 60 percent of HIV-infected individuals would benefit from immediate treatment with these drugs. In addition, the majority of people currently living with AIDS require expensive drug therapies.

Later in this chapter, the Commission discusses the impact of the Orphan Drug Act on the high cost of AIDS drugs and recommends amending the law to address this concern. The Commission also believes the Department of Health and Human Services should negotiate reasonable and accessible prices for drugs developed through NIH-funded research. This would reflect the federal government's contribution to the research and development costs normally undertaken by the private sector.

### PROVIDER REIMBURSEMENT

Public and teaching hospitals are an important source of care for low-income individuals who are uninsured or who have qualified for Medicaid. Owing to uncompensated care provided to the uninsured and low reimbursement rates under Medicaid, public hospitals have been experiencing significant economic losses when they provide care to AIDS patients. Private hospitals are treating more AIDS patients, but even they are experiencing financial strains.

As noted above, physicians have financial disincentives to provide care to individuals on Medicaid. Physician reimbursement rates under Medicaid are much lower than those from other third-party payers, and in the final analysis much care for HIV disease is entirely uncompensated. In this climate, not only may patients be forced to wait for care until serious symptoms develop, but they then are likely to be driven for lack of alternatives to seek care in the more expensive hospital emergency room or inpatient setting.

### INEFFICIENCY IN CURRENT CARE PATTERNS

There are marked inefficiencies in current patterns of care for people with HIV disease. One of the primary reasons inefficiency exists is the unfamiliarity of some providers with cost-saving regimens. Outpatient management of AIDS in the San Francisco area has been proven to have substantial cost savings (Hiatt et al., 1990). The use of AZT also has the potential for reducing annual costs while extending productive lives (Scitovsky et al., 1990).

> *Our state department of health currently provides AZT to persons with HIV infection providing they have an absolute CD4 cell count of five hundred or less. The department currently has twenty-three PWAs receiving AZT now and thirty-six on the list.*
>
> *Last week, we received word that continued additions to the waiting list may no longer be possible. I don't know what's worse; to tell someone they are number twenty-seven on a waiting list of thirty-six or to tell them we are no longer accepting names for the waiting list.*
>
> DONNA ANTOINE-PERKINS
> *July 1990*

*The first thing that immediately comes to mind is that what we have is a crisis of national health care. I mean, we have a health care system that is just not dealing with the health care needs of people who don't have private insurance.*

JIM GRAHAM, J.D., L.L.M.
*July 1990*

### IMPROVING HEALTH CARE FINANCING FOR PEOPLE WITH HIV DISEASE

The Commission believes that universal health care coverage is a necessary step toward addressing these obstacles and ensuring access to quality health care for all people living in the United States. This coverage should be comprehensive and should include prescription drugs. In the interim, the Commission recommends a series of immediate short-term steps to close the gaps in health care financing for those with HIV disease. In developing these recommendations, the Commission has sought to make incremental steps consistent with longer-term comprehensive reform. It has placed primary emphasis upon:

- encouraging greater access to health care, especially through early intervention and outpatient primary care;
- providing financing for a sufficiently broad range of health care benefits to avoid distortions and inefficiencies in patterns of patient care;
- assuring provider participation by setting payment rates at adequate levels, while avoiding large profits and open-ended escalating health care costs; and
- promoting equity and fairness by giving the greatest assistance to those most in need—the poor and those with catastrophically expensive illnesses.

These incremental recommendations focus primarily on the expansion of existing public health care financing programs rather than the expansion of employer-provided private insurance coverage. The Commission does not believe that an employer-based approach will be successful in meeting the needs of all people living with HIV disease. In part this is because many affected persons are outside the work force or are unable to continue working once the disease reaches an advanced stage. Furthermore, private insurers have been reluctant to shoulder a greater proportion of the financing burden, and regulatory attempts to force this burden on employers and insurers in the absence of more comprehensive reforms are likely to be circumvented.

#### Medicaid Expansion

The Commission recommends that legislation be enacted to expand Medicaid eligibility for low-income people with HIV disease. Currently, many people with HIV disease are not eligible for Medicaid even if they are poor. In addition to its poverty requirement, Medicaid is further limited to people who are (1) over 65; (2) members of families with dependent children; or (3) totally disabled. With HIV disease, this requirement generally limits Medicaid coverage to only those individuals who have a clinical diagnosis of AIDS. People who have tested HIV positive but have not advanced to a diagnosis of AIDS do not qualify, even if they meet the low-income eligibility requirements. This restriction renders poor people with HIV disease who do not have a clinical diagnosis of AIDS virtually ineligible for the early intervention treatments and services that can delay progression of HIV disease, prevent opportunistic infections, and limit numerous (and expensive) hospital visits.

The disability requirement for Medicaid should be eliminated for people with HIV disease. Although the Commission has made this recommendation specific to people with HIV disease, it can and should lead to further changes that will include people with other serious chronic illnesses.

The Commission also recommends that the income eligibility requirement for Medicaid be increased for people with HIV disease. Currently, an individual must actually be, or in some states be at risk of becoming, extremely poor to meet the income eligibility requirements for Medicaid. Many people with HIV disease are not impoverished but nevertheless do not have the health insurance or independent means to pay for the health care treatments and services they need. Therefore, either they are forced to rely on the already overburdened public hospital system for expensive inpatient care or they must spend themselves into poverty to qualify for Medicaid. Once impoverished and eligible for Medicaid, they become dependent on many other welfare programs for such basic needs as food, clothing, and shelter.

Eliminating the disability requirement at various income levels (including, in some instances, eliminating the asset test) would expand the number of people with HIV disease who would be eligible for Medicaid.

Eliminating the disability requirement for people with HIV disease and raising the current income eligibility to 100 percent of the federal poverty level would expand Medicaid coverage to include an estimated additional 6,800 low-income people with AIDS and 63,700 additional low-income people with HIV infection. This option would increase the total number of Medicaid recipients by less than half of one percent.

The overall estimated Medicaid cost of this option would be $345 million in FY 1991, and would be split between the federal government ($176 million) and state governments ($169 million). This option would result in an increase in total Medicaid expenditures of less than one percent.

If the income requirement were raised to 185 percent of the federal poverty level, with applicable asset tests, Medicaid would cover 91,000 people with HIV infection and 21,000 people with AIDS. The total cost for Medicaid would be $660 million and

> *I keep getting reoccurring infections, but I can't get Medicaid since I get $800 a month from my job. I have no health insurance. I can't get any. I had to deny health benefits in order to get my job.*
>
> LORELEI ESTRADA
> *June 1991*

would be split between the federal government ($337 million) and state governments ($323 million).

If the income requirement were raised to 200 percent of the federal poverty level, with no asset test, Medicaid would cover 103,200 people with HIV infection and 22,100 with AIDS. The total cost to Medicaid would be $727 million and would be split between the federal government ($371 million) and state governments ($356 million).

> *We have had to face the AIDS epidemic with our limited resources since the major financial subsidy for the indigent, Medicaid, has an island-wide annual cap of $79 million. This has restricted substantially the use of AZT, much needed by our AIDS patients.*
>
> PEDRO BORRAS, M.D.
> *November 1990*

Another incremental step would be to allow persons whose Social Security disability benefits render them ineligible for Supplemental Security Insurance (SSI) (because their disability payments are larger than the SSI income level permits) to keep their Medicaid coverage. In some cases, once a person becomes eligible for SSDI, they lose their eligibility for SSI and Medicaid and along with it, many of the health care services they need, particularly prescription drug coverage. Some states have opted to allow low-income SSDI recipients to keep their Medicaid coverage in order to expand Medicaid to the medically indigent. The Commission believes all states should exercise this option.

Medicaid payment rates for providers should also be increased sufficiently to ensure adequate participation in the Medicaid program. Unrealistically low reimbursement rates under the Medicaid program are serious disincentives for health care providers to care for people who rely on Medicaid. Medicaid payment rates for physicians, which currently average only 64 percent of Medicare rates, should be raised to Medicare levels.

Low reimbursement rates to hospitals may also contribute to an inequitable distribution of the HIV patient caseload. States should ensure that payment rates are adequate to cover the cost of efficiently caring for people with HIV disease.

To expand primary care to Medicaid beneficiaries with HIV disease, all community health centers and community clinics receiving Ryan White CARE Act funding, or similar sites meeting minimal federal standards, should be entitled to Federally Qualified Health Centers status. As a Federally Qualified Health Center, a provider would be eligible for reimbursement at 100 percent of reasonable cost under Medicaid. This would increase the availability of primary care in areas with large concentrations of people in need of care.

Special attention should be given to the concerns of the Commonwealth of Puerto Rico, where the HIV epidemic is intense and yet where there is a cap on total Medicaid expenditures, regardless of the growing needs of the population dependent on Medicaid. Because of the existing cap on Medicaid funds allocated to Puerto Rico, none of the Medicaid recommendations the Commission has put forward to expand benefits for people with HIV disease would include individuals living in this part of the United States. Congress and the Administration should work together to raise the Medicaid cap on funds directed to the Government of Puerto Rico to ensure equal access to care and treatment.

### COBRA Premiums

States and/or the federal government should pay the employer-based health insurance premiums for people with HIV disease who have left their jobs and cannot afford to pay their premiums. The Consolidated Omnibus Budget Reconciliation Act (COBRA) includes a provision to require employers with 20 or more employees to permit continued coverage if the insured are able to pay the premium. If the employee is disabled when he or she leaves a job, continued coverage must be allowed for 29 months. For people not disabled at the time they leave their jobs, continued coverage is for 18 months. This provision is designed to ensure health care coverage during the time a person would be waiting to become eligible for other health insurance or, if disabled, for Medicare. Many people with HIV disease cannot afford to pay the health insurance premiums (referred to as COBRA premiums) during the waiting period and are forced instead to spend themselves into poverty in order to become eligible for Medicaid.

Eight states and the District of Columbia have implemented some form of premium-paying program to cover the private individual or group health insurance premiums for individuals with chronic illnesses. The Commission believes all states and/or the federal government should pay the COBRA premiums for low-income people with HIV disease who have left their jobs and cannot afford to pay the health insurance premium.

If this option is limited to people with HIV disease who have incomes below the federal poverty level, it would extend employer-sponsored insurance to an estimated 2,000 people with AIDS and 8,000 people with HIV infection. Of the 2,000 people with AIDS receiving coverage under this option, 1,600 would have previously been eligible for Medicaid. (It is assumed that the low-income population cannot afford the COBRA premiums and would apply for Medicaid.) If the Medicaid income eligibility level is increased, that increased level should apply to this COBRA recommendation as well.

This option has the advantage of buying beneficiaries into private coverage, which is generally much more attractive than Medicare or Medicaid in terms of benefits covered and reimbursement rates. In addition, a comprehensive package of benefits is provided through many employer-sponsored group plans, which would include early intervention treatments.

The more generous reimbursement rates would be attractive to providers and people with HIV disease, who would not be required to change their source of care, as they would if they were covered under Medicaid and their physicians or hospitals did not participate in Medicaid. This option might take some of the burden of providing care away from the teaching and public hospitals and away also from those physicians who accept Medicaid patients.

This option results in a net savings to Medicaid because costs are shifted from the Medicaid program to employers through continuing coverage under employer-sponsored insurance plans. Overall FY 1991 savings to Medicaid would be $4 million for both people with HIV infection and people with AIDS. Of this, $28 million is saved for those with AIDS, whom otherwise Medicaid would have had to pay for, while the net cost is $24 million for people with HIV infection.

### Medicare Expansion

SSDI beneficiaries who are disabled and have HIV disease or another serious chronic health condition should have the option of purchasing Medicare during the current two-year waiting period. Medicaid would be required to purchase Medicare coverage for low-income SSDI beneficiaries.

This option would allow an estimated 10,500 SSDI beneficiaries with AIDS to purchase Medicare coverage. An estimated 4,900 would have their Medicare coverage purchased and supplemented by Medicaid; 5,600 would purchase Medicare on their own. Once eligible for SSDI, an individual would immediately be allowed to purchase Medicare coverage without having to wait out the 24-month waiting period. The annual cost to the beneficiary would be $3,559—the full actuarial cost for Part A (Hospital Insurance) and Part B (Supplemental Medical Insurance) premiums. In addition, beneficiaries would be liable for Medicare cost sharing and noncovered services such as prescription drugs. The cost to beneficiaries is therefore estimated to be $9,600 annually. Individuals with incomes above the federal poverty level would be expected to make these payments. Owing to the potentially large out-of-pocket cost to the individual, it is estimated that only 35 percent of the SSDI beneficiaries would take advantage of this option.

Private supplemental insurance policies (called Medi-gap policies) should also be opened up to people with HIV disease who can afford to purchase them. These policies are often the only way to cover the cost of prescription drugs and long-term care for Medicare beneficiaries.

There are significant gaps and cost sharing in the coverage provided by Medicare, which would put a heavy financial burden on many individuals purchasing Medicare under this option. Specifically, out-of-pocket costs for Part A include a deductible of $628 per episode of illness. Out-of-pocket costs for Part B, the coverage for physician and related services, include a deductible of $100 per year and coinsurance of 20 percent of the allowable Medicare charge. In addition, beneficiaries would be assessed a combined Part A and Part B premium of $3,559 per year. Figures are effective as of January 1, 1991.

Under Medicare Part A, individuals would be covered for inpatient hospital care, some inpatient skilled nursing facility care, home health care, and hospice care. Under Part B, they would be covered for physician services, outpatient hospital services, durable medical equipment, and other medical services and supplies. However, individuals would not be covered for prescription drugs, dental care, and a variety of long-term care services. The lack of prescription drug coverage would be particularly significant for some individuals because the annual cost of prescription drugs for people with AIDS averaged $4,400 in 1990 (Hellinger, 1991).

Despite these limitations in benefits, Medicare coverage will be attractive to many SSDI beneficiaries. Many are uninsured and unable to obtain private health insurance. Without Medicare they will be quickly driven into poverty or will do without needed care. A further benefit of Medicare coverage is that reimbursement rates higher than Medicaid's would act as an incentive for physicians to provide ambulatory care to individuals with HIV disease.

The cost of this option to the Medicare program is $220 million, in addition to payments paid by beneficiaries through premiums, deductibles, and coinsurance.

Such a change would result in a net savings to Medicaid of $78 million, since Medicaid would be used to purchase Medicare premiums for those individuals with incomes below the federal poverty level. Medicaid would continue to be used for paying coinsurance, deductibles, and for items not covered by Medicare, such as drugs for those currently eligible for Medicaid. Of the $69 million savings, approximately $35 million would be federal dollars and $34 million would be state dollars.

The Commission supports extending this option to SSDI beneficiaries with other serious chronic health conditions. Since all SSDI beneficiaries are by definition seriously disabled, they should be permitted the option of purchasing Medicare by paying the full actuarial cost of coverage during the two-year waiting period. This would extend coverage to an estimated 335,000 persons at an annual cost to Medicare of $1.2 billion and to Medicaid of $900 million.

> *Once I went to a hospital in New York City. They asked me if I had Medicaid. When they found out I didn't have any Medicaid they didn't want to help me. The nurse said, "Oh, your sores don't look that bad, I've seen worse." My legs hurt so bad I couldn't walk without the crutches I had stolen. They didn't even clean my sores, they just gave me antibiotics and put me out on the street to clean them myself. Now, how am I going to keep my sores clean when I was living in the subway ditch? You know how they are going to stay? Dirty.*
>
> RALPH HERNANDEZ
> *November 1989*

### The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act

The federal government should fund the Ryan White CARE Act at the fully authorized level. Creating the authority for federal programs to respond to the crisis of the HIV epidemic is one thing—actually providing the dollars to pay for them is another. While the Commission commends the Congress for establishing the Ryan White CARE Act programs, the Commission is very concerned about the small amount of money actually appropriated to implement the programs. Full funding is required to assure the availability and success of these desperately needed programs. The funds for the Ryan White CARE Act should be new money and not money shifted from other federal health and human services programs.

Full funding of the Ryan White CARE Act would encourage the provision of ambulatory care services to people with HIV disease by increasing compensation for outpatient care in hospitals, migrant and community health centers, community clinics, and other entities. This would increase support for hospitals in areas serving a disproportionate share of individuals with HIV disease, but it would also bolster migrant and community health centers and community-based organizations, which currently provide a substantial share of outpatient care for individuals with HIV disease. Financial relief for these institutions will enable them to care better for underserved and indigent patients. They are an important last resort for many uninsured people and for Medicaid patients who have difficulty finding providers willing to accept the Medicaid reimbursement rates.

This funding is earmarked for outpatient preventive services and clinical care. These alternative care strategies have been designed to reduce the number of unnecessary hospital admissions involving essentially preventable conditions such as *Pneumocystis carinii* pneumonia. Such outpatient care, if integrated into a larger network of services including mental health care, housing, family services, clinical care, and hospice care will ensure that patients receive services appropriate to their needs as their HIV disease progresses.

### INTERIM STEPS TO IMPROVE ACCESS TO EXPENSIVE DRUGS

There is a precedent for federal assistance with the cost of expensive HIV-related drugs. Prior to the Ryan White CARE Act, the federal government provided discretionary dollars, through the AIDS Drug Reimbursement Program, to each state to help pay for AIDS-related drugs. This program was expanded by some states and now, under the Ryan White CARE Act, all states and other eligible jurisdictions may use grant funds for this purpose.

The following interim steps should also be taken to improve access to expensive HIV-related drugs: (1) adequately reimburse patients for the purchase of drugs required in the prevention and treatment of HIV disease, including clotting factor for hemophilia; (2) undertake, through the Department of Health and Human Services, a program for the consolidated purchase and distribution of drugs used in the prevention and treatment of HIV disease; (3) amend the Orphan Drug Act to set a maximum sales cap for covered drugs.

### Adequate Reimbursement for HIV-related Drugs

While advances in treatments and technology have made more HIV-related drugs available, they are for many unaffordable. Many people lack health insurance and others have selective insurance policies that do not cover the cost of drugs (or at least the cost of certain kinds of drugs). In addition, state-funded programs operate on very limited budgets. Adequate reimbursements and improved payment mechanisms must be explored.

For example, advances in technology have made clotting factor for people with hemophilia free from HIV but at a tremendous economic cost. Virally attenuated clotting factor now costs $60,000 to $100,000 per year simply to meet the basic needs of one person with severe classical hemophilia. Three years ago the Presidential Commission on the HIV Epidemic recommended that the Health Care Financing Administration and Health Resources and Services Administration "develop alternative payment mechanisms to make clotting factor treatment affordable for patients." Notwithstanding this recommendation, nothing has been done. Meanwhile, insurers have become more selective, many patients have reached their lifetime caps on insurance, and state-funded programs to provide supplemental assistance are running into the same budget difficulties that are affecting every other state and local assistance program.

### Consolidated Purchase of HIV-related Drugs

A consolidated purchase of HIV-related drugs would enable the federal government to negotiate reduced costs for HIV drugs by offering pharmaceutical manufacturers volume sales. This could be done through a new mechanism involving a federal agency or through the Medicaid program. There are a number of precedents for this type of approach. One example is the federal purchase of childhood vaccines. The federal government, through CDC, buys childhood vaccines through negotiated open-ended contracts with large guaranteed minimum purchases. CDC offers this consolidated purchase option to the states on a voluntary basis. All fifty states have opted to participate in this program. By purchasing in bulk, the cost of a complete vaccination series is reduced by approximately 40 percent per child over the private-sector cost.

Medicaid programs in states that pay for prescription drugs currently pay the full retail price for HIV drugs.

With consolidated purchase, state Medicaid programs could opt to supply medications to Medicaid recipients at a negotiated reduced rate. The Medicaid program could be expected to save considerable sums on drug costs for Medicaid recipients. Lack of access to early intervention because of inability to pay for medication remains a significant barrier to care for the uninsured, whose care would therefore be particularly enhanced by this program.

The consolidated purchase approach is attractive for two reasons. First, there are precedents, such as the federal childhood vaccine program. Second, consolidated purchase could actually increase sales of AIDS drugs. The administrative cost would depend on the structure of a consolidated purchase program, but experience with the consolidated purchase of vaccines suggests that savings could be considerable.

### Amendment of the Orphan Drug Act

The high cost of drugs used in HIV treatment is explained in part by their patent protection and "orphan drug" status. The Orphan Drug Act of 1983 was intended to encourage development of drugs for treating small numbers of people with rare diseases (Asbury, 1991). It provides financial incentives, tax breaks, and a seven-year exclusive right to the drug's market.

Although drug companies' expectation of recouping investments in research and development and realizing a profit is legitimate, it is also legitimate for the public to expect a reasonable price for lifesaving drugs. Frequently cited examples of drugs granted orphan drug status that have subsequently generated considerable sales and profits include AZT, aerosolized pentamidine, recombinant human growth hormone, and recombinant erythropoietin (EPO) (Thoene, 1991). EPO, although principally used for patients who are suffering from renal disease, is also used to treat HIV-related anemia. Of the aforementioned drugs, only pentamadine (with 1990 sales estimated at $480 million) would be clearly affected by reform of the orphan drug law, since the others are currently protected by patent law beyond the seven-year exclusivity of orphan status (Asbury, 1991). Reform of the Orphan Drug Act, however, could affect other drugs still under research, as well as orphan drugs used in other diseases.

Reform of the Orphan Drug Act through a cap on sales or profits has a number of implications. It would deny orphan status to a drug once it had proved very profitable, while retaining orphan status for small market or unprofitable drugs. Thus, one result would be to return the application of the law to its original intent. Further, by preserving orphan status until a drug has achieved high profitability, manufacturers could still recover the cost of research and development phases of a new drug for a rare disease; thus, research incentives would not be lost. For a previously approved drug granted orphan status for a new indication (as was the case for pentamidine), the loss of orphan status once high profitability was established would mean the loss of exclusivity for that drug and for that indication. Market forces would then be expected to lower costs.

This proposed approach has an advantage over a population limit for orphan drugs in that it is based on a demonstrable end point (profits or sales), whereas population targets are likely to be based on figures (such as the number of HIV-infected individuals) subject to considerable debate. A sales cap of $150 million dollars has been suggested by the National Organization of Rare Disorders. This option attempts to return the Orphan Drug Law to its original intent, and would not affect drugs with low sales or profits.

This proposal could result in considerable savings for all payers of drugs for treatment of HIV disease. Savings on pentamidine alone could amount to $900 per patient per year; administrative costs would be minimal. Such a policy would not be AIDS-specific and would be expected to benefit any patient group requiring an expensive orphan drug whose price was affected by the amendment.

The Commission firmly believes that total systemic reform will be necessary to genuinely achieve appropriate access to health care for all people living in the United States. In the interim, the Commission recommends a series of immediate short-term steps to address the urgent problem of inadequate coverage for people with HIV disease.

# RECOMMENDATIONS

1. **Universal health care coverage should be provided for all persons living in the United States to ensure access to quality health care services.**
   The Commission believes universal health care coverage is a necessary step to ensuring access to quality health care. This coverage should be comprehensive and should include prescription drugs. In the interim, the Commission recommends a series of immediate short-term steps to address the urgent problem of inadequate coverage for people with HIV disease.

2. **Medicaid should cover all low-income people with HIV disease.**
   The Commission recommends eliminating the disability requirement and raising the income level for Medicaid eligibility for people with HIV disease. By eliminating the disability requirement, low-income people with HIV infection who have not had a clinical diagnosis of AIDS could be covered by Medicaid and receive the early intervention treatments and services they need. Increasing the income eligibility requirement would prevent many people with HIV infection from having to impoverish themselves in order to qualify for basic health care services. At the same time it would relieve some of the reliance on public hospitals by the uninsured.

   The Commission strongly believes these changes should be mandated; however, at the very least, states should be given the option of making these changes. In addition, the Commission believes these changes can and should lead to further changes that will include people with serious chronic conditions other than HIV disease.

3. **Medicaid payment rates for providers should be increased sufficiently to ensure adequate participation in the Medicaid program.**
   Unrealistically low reimbursement rates under the Medicaid program serve as a serious disincentive for health care providers to care for people who rely on Medicaid. Medicaid rates should be raised to Medicare levels.

4. **Congress and the Administration should work together to adequately raise the Medicaid cap on funds directed to the Commonwealth of Puerto Rico to ensure equal access to care and treatment.**
   Because of the existing cap on Medicaid funds allocated to the Commonwealth of Puerto Rico, none of the Medicaid recommendations the Commission has put forward to expand benefits for people with HIV disease would include individuals living in this part of the United States.

5. States and/or the federal government should pay the COBRA premiums for low-income people with HIV disease who have left their jobs and cannot afford to pay the health insurance premium.

6. Social Security Disability Insurance (SSDI) beneficiaries who are disabled and have HIV disease or another serious chronic health condition should have the option of purchasing Medicare during the current two-year waiting period. Medicaid should be required to purchase Medicare coverage for low-income SSDI beneficiaries.

7. The federal government should fund the Ryan White CARE Act at the fully authorized level.

8. The following interim steps to improve access to expensive HIV-related drugs should be taken:
    (a) adequately reimburse for the purchase of drugs required in the prevention and treatment of HIV disease, including clotting factor for hemophilia;
    (b) undertake, through the Department of Health and Human Services, a consolidated purchase and distribution of drugs used in the prevention and treatment of HIV disease;
    (c) amend the Orphan Drug Act to set a maximum sales cap for covered drugs.

## SELECTED BIBLIOGRAPHY

Andrulis, D.P., V.B. Weslowski, and L.S. Gage. 1989. The 1987 U.S. hospital AIDS survey. *Journal of the American Medical Association* 262:784–794.

Antman, K., L.E. Schnipper, and E. Frei. 1988. The crisis in clinical cancer research, third party insurance and investigational therapy. *New England Journal of Medicine* 319:46–48.

Arno, P.S., and D. Shenson. 1990. "From AIDS to HIV Disease: Transformation of an Epidemic." In *Community–Based Care of Persons with AIDS: Developing a Research Agenda.* Washington, D.C.: U.S. Government Printing Office.

Arno, P.S., D. Shenson, N.F. Siegel, P. Franks, and P.R. Lee. 1989. Economic and policy implications of early intervention in HIV disease. *Journal of the American Medical Association* 262:1493–1498.

Asbury, Carolyn. 1991. "The Orphan Drug Act: The first 7 years." *Journal of the American Medical Association* 265(7):893–897.

Benjamin, A.E. 1988. Long-term care and AIDS: Perspectives from experience with the elderly. *Milbank Quarterly* 66:415–443.

Bloom, D., and G. Carliner. 1988. The economic impact of AIDS in the United States. *Science* 239:604–610.

Centers for Disease Control. 1990. HIV prevalence estimates and AIDS case projections for the United States: Report based upon a workshop. *Morbidity and Mortality Weekly Report* 39(RR-16):1–31.

Centers for Disease Control. 1991. Mortality attributable to HIV infection/AIDS—United States, 1981–1990. *Morbidity and Mortality Weekly Report* 40:41–55.

Davis, K., R. Bialek, C. Beyrer, P. Chaulk, P. Cowley, and J. Harlow. 1991. *Financing Health Care for Persons with HIV Disease: Policy Options.* A Technical Report Prepared for the National Commission on AIDS. Baltimore, Md.: Johns Hopkins School of Hygiene and Public Health, August 26.

Fox, D.M. 1990. Chronic disease and disadvantage: The new politics of HIV infection. *Journal of Health Politics, Policy and Law* 15:341–355.

Fox, D.M., and E.H. Thomas. 1990. The cost of AIDS: Exaggeration, entitlement, and economics. In L.O. Gostin, ed., *AIDS and the Health Care System.* New Haven, Conn.: Yale University Press.

Gage, L.S., V.B. Weslowski, D.P. Andrulis, E. Hintz, and A.B. Camper. 1991. *America's Safety Net Hospitals: The Foundation of Our Nation's Health System.* Washington, D.C.: National Association of Public Hospitals.

Gail, M.H., and R. Brookmeyer. 1988. Methods for projecting course of Acquired Immunodeficiency Syndrome epidemic. *Journal of the National Cancer Institute* 80:900–911.

Green, J., and P.S. Arno. 1990. The "Medicaidization" of AIDS: Trends in the financing of HIV-related medical care. *Journal of the American Medical Association* 264:1261–1266.

Griggs, J., ed. 1989. *Simple Acts of Kindness, Volunteering in the Age of AIDS.* New York: United Hospital Fund of New York.

Health Care Financing Administration, Office of the Actuary. 1990. *Financing Health Care for People with AIDS: The Role of the Health Care Financing Administration.* Washington, D.C.: U.S. Government Printing Office.

Hellinger, F.J. 1990. Forecasting the medical care cost of AIDS. Paper presented at the Sixth International Conference on AIDS, San Francisco, Calif., June 20–24.

Hellinger, F.J. 1990. Updated forecasts of the costs of medical care for persons with AIDS, 1989-93. *Public Health Reports* 105:1–12.

Hellinger, F.J. 1991. Forecasting the medical care costs of the HIV epidemic in the United States: 1991-1994. Paper presented at the Seventh International Conference on AIDS, Florence, Italy, June.

Hiatt, R.A., C.P. Queensberry, J. Selby, B. Fireman, and A. Knight. 1990. The cost of acquired immunodeficiency syndrome in Northern California: The experience of a large prepaid health plan. *Archives of Internal Medicine* 150:833–838.

Iglehart, J. 1987. Financing the struggle against AIDS. *New England Journal of Medicine* 317:180–184.

Intergovernmental Health Policy Project. 1990. State financing for AIDS: Options and trends. *Intergovernmental AIDS Reports* 3:1–8,12.

Lambert, B. 1989. Insurance limits growing to curb AIDS coverage. *New York Times.* August 7:A1, A10.

Makadon, H.J., G.R. Seage, K.E. Thorpe, and H.V. Fineberg. 1990. Paying the medical cost of the HIV epidemic: A review of policy options. *Journal of Acquired Immune Deficiency Syndrome* 3:123–133.

Merlis, M. 1990. *Acquired Immune Deficiency Syndrome (AIDS): Health Care Financing and Services.* Issue Brief 87219. Washington, D.C.: Congressional Research Service.

Oppenheimer, G.M., and R.A. Padgug. 1991. AIDS and the crisis of health insurance. In F. Reamer, ed., *AIDS and Ethics.* New York: Columbia University Press.

Padgug, R.A., and G.M. Oppenheimer. 1990. AIDS, health insurance, and the crisis of community. *Notre Dame Journal of Law, Ethics and Public Policy* 5:35–51.

Rango, N., I. Feldman, G. Burke, E. Anderson, and S. Anderman. 1990. Enhanced Medicaid rates for the treatment of HIV. Paper presented at the Sixth International Conference on AIDS, San Francisco, Calif., June 20–24.

Roper, W.L., and W. Winkenwerder. 1988. Making fair decisions about financing care for persons with AIDS. *Public Health Reports* 103:305–308.

Rowe, M., and R. Keintz. 1989. National survey of state spending for AIDS. *Intergovernmental AIDS Reports* 2:1–10.

Scitovsky, A. 1988. The economic impact of AIDS in the United States. *Health Affairs* 7:32–45.

Scitovsky, A.A. 1989. Studying the cost of HIV-related illnesses: Reflections on the moving target. *Milbank Quarterly* 67:318–344.

Scitovsky, A.A., M.W. Cline, and D.I. Abrams. 1990. Effects of the use of AZT on the medical care costs of persons with AIDS in first 12 months. *Journal of Acquired Immune Deficiency Syndrome* 3:904–912.

Sisk, J. 1987. The costs of AIDS: A review of the estimates. *Health Affairs* 6:5–21.

Stone, D.A. 1990. AIDS and the moral economy of insurance. *American Prospect* Spring:62–73.

Thoene, J.G. 1991. Curing the orphan drug. *Science* 251:1158–59.

Yelin, E.H., R.M. Greenblatt, H. Hollander, and J.R. McMaster. 1991. The impact of HIV-related illness on employment. *American Journal of Public Health* 81:79–84.

Sheila Swain

*I have a son who is infected with HIV. . . . He was doing very well, up until a couple of months ago. He had to have his tonsils removed. And since then, he's been very tired and just—he's worn out. And he's just tired of fighting this whole thing. But he'll hear these little things from people, from school, from the media. "I heard about a miracle cure." He came home saying, "Mom, I heard about this cure. You know, can we check on it? Can we go somewhere in France or something? It comes from some snake's head or something—you know." And he gets his hopes up so much.*

*And just today when I called to see how he was, he said, "Did you testify yet? Did you tell them?" He said, "Did you tell them to hurry up and find a cure?" What do I tell him? What do I tell him now? I mean he knows ddI is helping him but now what do I tell him when he hears there's something going on in France that is definitely a cure? "It's a real cure, Mom. It is. That's what they're saying."*

*How do I explain to him that it's maybe not? What do I tell him? What happens after ddI? I don't know. I don't have the answers. I know what I need to tell him, but I don't. I can't. He wants to have hope. I want to have hope, but I don't see any hope on the horizon as far as a vaccine goes. He was so excited about a vaccine and I said, well, that wouldn't really help you. It would help other people like us—like your brothers and myself who aren't infected. And he said, "So it wouldn't do a damn thing for me, huh?"*

*I mean, he deals with it very, very well. But he's starting to see the injustice and the prejudices and I know it's got to hurt. It's got to hurt, but he handles it so well. I don't know, I don't know how he does it. I just think he's a remarkable child.*

SHEILA SWAIN
*March 1991*

## CHAPTER FIVE

# CLINICAL TRIALS AND TREATMENT-RELATED RESEARCH

The following chapter deals exclusively with clinical trials and related issues of drug development. Such focus should not be construed as an indirect statement about the relative importance of various other research endeavors. In fact, the Commission recognizes and appreciates the importance of the larger biomedical research enterprise and the enormous contributions it has made to all diseases, particularly HIV disease. This chapter focuses particularly on the extensive attention and input on clinical trials and drug development that occurred during months of Commission hearings and discussions with people living with HIV disease and their caregivers. Clearly, other areas of research are of critical importance (particularly vaccine studies and behavioral and social science research), and the Commission will be focusing attention on these areas in the coming year.

## OVERVIEW

The lack of primary health care services for many people with HIV disease has forced them to look to clinical trials for basic primary care, as well as for access to experimental treatments. Although the Commission firmly believes access to experimental treatments is an essential component of health care services for all people with HIV disease, the Commission also believes that obstacles to receiving primary care outside the clinical trial setting must be addressed so that the research setting is not the only place of access for experimental treatments. The Secretary of Health and Human Services should direct the National Institutes of Health (NIH), the Health Care Financing Administration (HCFA), and the Health Resources and Services Administration (HRSA) to work together to develop a series of recommendations to address the obstacles that keep many people from participating in HIV-related clinical trials, as well as the variables that force some people to seek participation in trials because they have no other health care options.

For people with HIV disease, access to experimental treatments is an essential component of their basic health care needs. The fast pace of HIV-related research often results in experimental therapies becoming the standard of care for people with HIV disease. Experimental drugs are the only option for many. Access to these drugs through traditional clinical trial programs and the community-based clinical trials program, as well as new expanded access programs, is imperative.

New safe and effective drugs to treat HIV disease are urgently needed. Although there are some drugs currently available that either attack the human immunodeficiency virus (HIV) or treat or prevent the many opportunistic infections that characterize HIV disease, these drugs are, at best, half-way measures. They may extend life and minimize suffering of people with HIV disease, but they are far from a cure. Currently available HIV treatment drugs are expensive and the means of delivering them may be cumbersome, involving aerosolizers or intravenous infusions. All of these factors may present barriers to those who could benefit from their use. HIV treatments may also be toxic; some patients are unable to tolerate certain drugs. Without new safe and effective drugs, many thousands of people living with HIV disease face suffering and death.

In this chapter the Commission looks at how HIV-related clinical trials have been conducted, highlights ways in which access to these trials can and should be improved, and explores ways in which the drug development and approval process can make experimental drugs more accessible to people with HIV disease.

## CLINICAL TRIALS

Typically it takes many years to get drugs from the laboratory bench to the pharmacy. This process includes extensive laboratory testing, animal testing for safety, and early human testing. This sequence of carefully designed scientific methods also includes a regulatory process to ensure the safety and efficacy of drugs. These methods and processes have long been in place to ensure that information is accurate and that drugs are safe. For many in need of these potentially life-saving therapies, this process can be lengthy, laborious, and frustrating.

Examples abound of drugs, widely believed to be effective, that were proved ineffective or even harmful when subjected to rigorous scientific study. In fact, the brief history of the HIV epidemic includes several examples of such drugs, such as suramin, which actually hastened the death of people with AIDS, and dextran sulfate, which was used widely before it was learned that it was not absorbed into the body when taken orally.

The double-blind, placebo-controlled, randomized clinical trial has long been considered the most reliable method for evaluating new medical interventions. It has often been regarded as the "gold standard" for the establishment of efficacy of proposed new medical treatments. In ideal circumstances, efficacy protocols would include strict entry criteria defining a subject's stage of disease, age, and health status, and would be designed to minimize the number of confounding variables posed by other disease conditions or drug interactions. Many scientists believe such study designs offer the most rapid answers to the question of how well a therapy works.

The HIV epidemic, however, has prompted a reassessment of the methods of clinical research and the use of placebo controls. It has brought a new sense of urgency and concern about the appropriate balance between the need to bring new, safe, and effective drugs to market for treating life-threatening illnesses and the need to protect the welfare of experimental subjects, many of whom see access to these unproven therapies as their only hope. Some consider this access to experimental therapies a right. The HIV epidemic has also brought a recognition that the validity of the scientific process itself depends upon the ability to translate scientific findings to the real world.

The strict entry criteria traditionally associated with the controlled clinical trial have excluded many who wish to participate in HIV-related trials. Women, drug users, people with hemophilia, and children, among others, were initially excluded from HIV-related trials because they did not meet the strict entry criteria for participation. Such criteria made access to experimental therapies virtually impossible for whole communities of people with HIV disease. (Later in this chapter the Commission identifies obstacles to participation in trials that still exist for people of color, women, children, drug users, people with hemophilia, and prisoners.) The appropriate medical management of people with HIV disease often involves the use of many different drugs at one time. Each new complication of HIV disease and its prevention or treatment makes entry into a classically designed clinical trial difficult since the classically designed protocol would attempt to minimize the number of variables posed by other disease conditions or drug interactions.

> *Recently I met a woman physician who agreed with me that I may be experiencing symptoms indigenous to women. Read my lipstick—women do not have the same symptoms as men.*
>
> SONIA SINGLETON
> *May 1990*

Efforts have been made to address the concerns expressed by many about the strict entry criteria for participation in controlled clinical trials. The Commission believes these efforts should continue and be expanded, since greater participation by traditionally excluded groups will not only provide increased access to experimental therapies for many people with

HIV disease but will also contribute to a better understanding of how certain experimental drugs will actually work outside a scientifically controlled environment.

The Commission believes controlled clinical trials are an essential part of any comprehensive clinical research program. Placebo controls are warranted in clinical research when no other effective therapy exists, but where effective therapies do exist, comparison of new therapies to those proven effective are considered appropriate. The realities of HIV disease demand that creativity and flexibility in designing and implementing the trials are equally essential. Input from representatives of affected communities at the earliest stage of study design can minimize misunderstandings and improve participation in trials. The importance of autonomy and patient choice, long a central theme of discourse about the ethics of human subjects research, should be underscored. People with HIV disease have sought and disseminated information in order to make informed choices about whether they wish to assume the risk of participation in research. People with HIV disease have also sought greater involvement on research-related advisory councils. This involvement is now reflected by the participation of people with HIV disease on many decision-making councils of the National Institutes of Health, the Food and Drug Administration, the Institute of Medicine, Institutional Review Boards, and other such bodies. The Commission believes the involvement of people with HIV disease on all of these councils and advisory bodies has and will continue to enhance HIV-related research programs. The Commission particularly encourages the involvement of people of color on these bodies and advisory councils.

*The strategy for treatment is threefold: treating the complications of HIV, be they opportunistic infections or neoplasms; direct antiviral therapy; and ultimately, if we are successful, to reconstitute the diminished immune response, which, as you could imagine, is something that is really quite complex.*

ANTHONY FAUCI, M.D.
*May 1990*

The National Institutes of Health, in particular the National Institute on Allergy and Infectious Diseases (NIAID), sponsors most of the clinical research on HIV. The AIDS Clinical Trials Group (ACTG) is a national program administered by NIAID which sponsors HIV-related clinical trials in academic institutions around the country. Included in this national program is an “ACTG-without-walls concept” that specifically conducts clinical studies for people with hemophilia.

The ACTG Program has received considerable scrutiny and criticism over the past few years from a number of individuals and organizations including ACT-UP, the People with AIDS Coalition, members of Congress, the Institute of Medicine, and advocates for women, children, and prisoners, among others. In its Third Interim Report to the President and the Congress, the National Commission on AIDS also expressed a great deal of concern about the ACTG program. The Commission was particularly concerned about the underrepresentation of people of color and women in HIV-related clinical trials. The Commission is pleased to note that NIH has increased the participation of people of color and women in their ACTG trials, and strongly recommends that these current efforts be continued and increased.

NIAID also sponsors the Community Programs for Clinical Research on AIDS (CPCRA). These programs are designed to encourage the participation of persons currently underrepresented in the ACTG Program in well-designed trials. It is important to note that this program should serve as an additional research opportunity for underrepresented communities and not as a substitute for their participation in ACTG trials. The program is also designed to utilize the considerable expertise and energy of community-based physicians and organizations for the conduct of sound research. The Commission continues to consider this to be an imaginative and effective program that should be continued and expanded in parallel with steps necessary to strengthen the ACTG Program. The Commission also strongly supports CPCRA's emphasis on the prevention and treatment of opportunistic infections as the highest scientific priority of the program.

The appropriate balance between research on antiviral drugs (aimed at HIV, the underlying cause of AIDS) and drugs targeted for treatment and prevention of the many opportunistic infections associated with HIV disease has also been a topic of much discussion and concern for many people with HIV disease, for members of the research community, and for the National Commission on AIDS. The Commission continues to believe that both areas of research are vitally needed and that the dollars to ensure both are essential. Congress should provide sufficient funding to enable NIH to give greater priority to research related to opportunistic infections without undermining research on antiviral drugs.

Sufficient funding is essential for all HIV-related research activities to protect against shifting funds from one vital area of research to pay for another. The development of an NIH plan, as recommended by the Institute of Medicine in its study of the AIDS Research Program of NIH, would go a long way toward helping to identify and plan for HIV-related research priorities and funding needs.

## DRUG DEVELOPMENT AND APPROVAL

The Food and Drug Administration (FDA) is the federal government agency with the responsibility to ensure that drugs meet standards of safety and efficacy before they are marketed. FDA does not initiate drug development, but rather its regulatory decisions can determine which drugs (developed by the pharmaceutical industry, or the government, or both) reach the marketplace.

During much of the HIV epidemic FDA has been criticized for not acting

*Some of you*
*will tell me that, in the world*
*of drug research and approval,*
*it's never gone so quickly as*
*it has with AIDS; I will tell you*
*that in some neighborhoods*
*of this country people have*
*never died so often so young*
*of diseases so ugly as*
*cryptosporidiosis, of MAI, or of*
*a peripheral neuropathy. . . .*
*Give us this day our daily*
*death and forgive me*
*if I sometimes sound bitter.*
*But I have a face in my mind*
*for every AIDS-related*
*condition I can describe to you,*
*and sometimes several faces,*
*every one the face of a friend*
*either living or dead. . . .*
*When the process by which we*
*test and approve therapies*
*is so suffocatingly slow,*
*I can see little quick relief from*
*the cycle of sickness and death*
*that for a decade now has*
*drained my community and*
*rendered our culture*
*incalculably poorer.*

JIM EIGO, M.F.A.
*May 1990*

quickly enough to approve drugs for use in treating HIV disease. Much of this criticism has come from people with HIV disease. However, there has long been criticism of FDA for the length of the drug approval process by proponents of deregulation who consider the drug lag to be evidence of excessive red tape. In fact, recently the National Committee to Review Current Procedures for Approval of New Drugs for Cancer and AIDS (referred to as the "Lasagna Committee" after its Chairman Louis Lasagna, M.D.) reviewed FDA activities. In its August 1990 report, the Committee called for less stringent criteria of effectiveness and recommended that FDA "be more flexible and permit the use of treatment earlier in the [regulatory] process where alternative therapies are unavailable."

There is a great deal of debate over how much and what kind of data must be required before FDA will approve a drug for marketing; but not all of the roadblocks to getting drugs to the marketplace involve philosophical or scientific disagreements with FDA. FDA has been grossly underfunded and as a result has been hampered by a lack of trained scientists, as well as by insufficient facilities and equipment needed to review quickly the data submitted by clinical researchers. Clearly, FDA needs funds and personnel commensurate with its important mission to safeguard the public health, and in the context of HIV disease, to speed up the pace of drug approval. The Commission strongly urges the Congress and the Administration to review FDA's budget and provide the funding increases needed to meet the demands placed on the agency.

### EXPANDED ACCESS STRATEGIES

From the beginning of the modern era of drug development regulation in the early 1960s, there have been provisions for distributing potentially lifesaving drugs, not yet licensed for use, to seriously ill individuals. Since that time, it has been possible for physicians to gain access to drugs under study through investigational new drug (IND) applications ("compassionate use" INDs or investigator INDs). The rules governing such access were never completely codified; the result was an informal process that relied heavily on the ingenuity and energy of individual physicians.

In 1987 the IND regulations for drug trials in serious illnesses were updated. The regulations allowed patients with serious or life-threatening conditions to receive drugs under any phase of investigation if there was evidence that they "may be effective." There was much debate about the interpretation of these regulations in practice as they applied to HIV disease. These problems led to the search for a mechanism that would allow for widespread distribution of promising drugs while they are still under study. This alternative mechanism was dubbed the "parallel track" because it facilitated early access to experimental therapies for people who did not qualify for inclusion in protocols, in parallel with ongoing, traditional clinical trials.

The parallel track permits the use of a drug as early as the end of a phase one clinical trial for all patients who are not eligible for conventional clinical trials or treatment INDs, and for whom no alternative treatments exist. In May 1990, the parallel track proposal was published in the *Federal Register* for public comment. These comments were reviewed by the Public Health Service in September 1990; the Commission awaits the promulgation of a formal policy.

The expanded access arm of the parallel track system was not designed to yield reliable information about the *efficacy* of drugs under treatment. There are no control groups and the use of historical controls (retrospective comparisons to untreated populations, matched by clinically relevant characteristics) is made difficult by the complex nature of HIV disease and the rapidly changing treatments that strongly influence the "natural history" of the disease. However, data from the expanded access arm may, if collected properly, be useful in monitoring safety and in providing information about drug interactions and resistance. The downside of this potential is that data collection requirements continue to be a concern for beleaguered primary care physicians and a stumbling block to greater access.

Furthermore, once a drug is widely available, it may be difficult to rebut intuitive but poorly substantiated belief in its effectiveness. Drugs introduced for narrowly defined patient groups often gain adherents for broader usage that may not be warranted.

Two questions concerning the success of expanded access programs should be posed: (1) Are promising drugs getting to the widest possible group of those in need? and (2) Is sufficient information being gathered to allow researchers to determine whether drugs are truly effective? The experience with expanded access programs for dideoxyinosine (ddI) and dideoxycytidine (ddC) may partially answer these questions.

There are also a number of other proposals to expand access to experimental drugs, ranging from broadening the range of treatment INDs to conditional approval. FDA should aggressively pursue all options for permitting the early use of promising new therapies for conditions for which there is no standard therapy or for patients who have failed or are intolerant of standard therapy.

## DISSEMINATING INFORMATION CONCERNING RESEARCH

A repeated concern of people with HIV disease about AIDS drug trials has been delay in getting information about promising new drugs to physicians and their patients in need. There are a number of possible venues for the release of information about potential breakthroughs in treating HIV disease. Peer-reviewed journal articles have a major advantage over most of the alternative means of distributing information, especially the "science by press release" process. Side effects, numbers of subjects, study design, and potentially important caveats are usually overlooked when "breakthroughs" are announced. However, some researchers have withheld critical data while awaiting acceptance for publication in peer-reviewed medical journals. A number of journals follow the "Ingelfinger rule" (named after a former editor of the prestigious *New England Journal of Medicine*) enforcing a news embargo during consideration of articles and prior to publication of research results. However, in the context of the HIV epidemic many journals have amended that policy and now recognize exceptions for information of urgent importance to the public health.

The main problem with journal publication of important findings about treatment for HIV disease, including zidovudine (AZT), aerosolized pentamidine, and corticosteroids, is that publication has lagged as many as nine months behind less conventional communications such as press conferences, press releases, or abstracts presented at scientific conferences. This delay is difficult to understand for people whose survival may be measured in months or a few years.

A number of solutions have been proposed, including: revising the timelines for submitting, reviewing, and accepting articles in peer-reviewed publications; making articles available on-line as soon as they are accepted (even prior to actual publication); and encouraging a standard format for release of information to the press.

There is a significant role for federal agencies to play in disseminating information about promising new treatments for HIV disease. Each of the following groups has an important role to play: the National Cancer Institute (which administers the Physician Data Query Service), FDA (which publishes the *FDA Drug Bulletin* and places columns in a number of leading medical journals), the National Library of Medicine, the Health Resources and Services Administration (which funds the AIDS Education and Training Centers' program to educate health care providers about

AIDS), and the Agency for Health Care Policy and Research. These avenues deserve exploration, since the merits of peer review per se are substantial and minimizing delay thus becomes the strategy of choice.

The Commission recognizes that efforts have been made at NIH to facilitate and accelerate the dissemination of new information concerning therapeutic interventions and alternatives for people living with HIV disease, including the AIDS Clinical Trials Information System and Clinical Trials Alerts. In addition, the January 1991 workshop on expedited dissemination of information and the July 1991 meeting of a panel convened to develop guidelines on distributing information are clearly steps in the right direction. The Commission urges, however, that the worthy objectives of these panels be imbued with the sense of urgency appropriate to the status of people progressing through stages of HIV disease and in need of intervention.

### ACCESS TO CLINICAL TRIALS FOR POPULATIONS IN NEED

Some individuals and communities affected by HIV disease have experienced considerable obstacles to participation in trials, and the Commission wishes to highlight them specifically.

Intravenous drug users are often wrongly assumed to be unwilling or unable to comply with research protocols. In addition, they often have other health problems that complicate studies. Many lack access to primary care and, therefore, the information and opportunity to participate in a trial.

People of color have concerns about exploitation that has taken place in the research context in the past. The Commission heard powerful testimony about the shadow of the Tuskeegee syphilis study and the significant impact the remembrance of this disturbing incident has had on views of many African-Americans regarding clinical research. Much must be done about the antipathy for research felt by many people of color. Increasing the number of racial and ethnic minority health professionals would be an important step toward addressing this concern. Every effort must be made to identify, nurture, and support researchers indigenous to the communities they serve.

As mentioned earlier in this chapter, women, particularly women of color, have traditionally experienced difficulty in qualifying for clinical trials. Obstacles to their participation, including the need for transportation and daycare, should be carefully examined and addressed.

> *During the recent NIAID conference on HIV infection and women, some observers criticized health officials and researchers for seeing women with AIDS mainly as vectors for the transmission of the disease to their male partners or children, rather than as a center of attention in their own right. In a way, this same question hovers, unasked, around many discussions of AIDS in the African-American community. Many in the African-American community wonder about expressions of distress over AIDS among Black Americans in the face of such remarkable inattention to and disregard for the health status of the Black community in general: "Are they interested in the spread of AIDS because they are concerned about us, or are they interested in us only because they are concerned about the spread of AIDS?"*
>
> MARK SMITH, M.D., M.B.A.
> *December 1990*

While the Commission recognizes that lack of access to health care seriously hampers efforts to recruit underrepresented people into clinical trials, this does not mean it is impossible to do so. Current efforts at NIH to expand the recruitment of underrepresented populations in the ACTG have enjoyed initial success and should be continued and increased.

> *Our medical systems, of course, are going to have to address ways of trying to keep pace with this disease, not only in terms of providing care, but equally importantly in training individuals who will be able to lead the research effort as well as the clinical care demands of the future. We will have to bear the financial burdens for this treatment and research. In addition the pediatric population also faces potential discrimination, which may increase in the future.*
>
> PHILIP PIZZO, M.D.
> *May 1990*

Children with HIV disease also have many problems with access to experimental treatments; again, some problems are unique to HIV and others are not. The vulnerability of children raises special concerns about placing them at risk in experimentation, even when there are potential therapeutic benefits for the individual children involved or for similarly situated children. However, as the Commission pointed out in its Third Interim Report, science has moved forward to the point where the inclusion of children in experimental HIV therapies is clearly possible.

Pediatric pharmacology can differ substantially from that of mature adults. Put succinctly, children are not miniature adults in regard to the types and dosages of drugs needed for treatment of HIV disease. As with all research involving children, their limited understanding and capacity to consent means that proxy decision makers, such as parents or other guardians, must speak on their behalf. In some cases, this raises further concerns because of the fragile family and social settings in which children with HIV disease are likely to be found. Aside from a small fraction of transfusion-related cases, virtually all HIV-positive children have mothers who are themselves infected with HIV and may be sick and dying. These mothers, with limited means and waning energy, are hard-pressed to find health care for both themselves and their children and may have serious difficulty in conforming to diverse research protocols. Many young children with HIV disease are cared for by relatives other than their parents or are placed in foster care. It may be difficult to secure the necessary consents for experimental HIV care; parents who relinquish custody do not necessarily give up decisionmaking rights regarding health care.

Concerns about scientific issues and the vulnerability of children as research subjects must be carefully balanced with children's need for, and right to participate in, research into promising new drugs. The Commission encourages efforts to address the special needs of the growing number of children with HIV disease.

People with hemophilia who live far from any ACTG or who are perceived of as having co-morbidities of bleeding and liver disease are also often excluded from trials. Such exclusions should be carefully examined and the judgment of the person's physician should be respected.

Prisoners' participation in clinical trials has been hampered by a serious confusion about the applicability of federal regulations designed to protect prisoners from experimentation abuses. Many have assumed that human subject regulations and prior ethical analysis all but preclude prisoners' participation as clinical trial participants; commentators have interpreted these regulations to preclude only prisoners' participation on the placebo arm of clinical trials. Practical considerations also pose formidable barriers for prisoners. It is difficult to ensure voluntariness and informed consent in the prison setting. Clinical researchers in academic and community settings may find the regulatory, ethical, and logistical stumbling blocks too daunting even to attempt enrolling prisoners in trials.

Concerns about research in correctional facilities, discussed in the Commission's Fourth Interim Report, warrant close attention because of the increasing number of people living with HIV in correctional settings. The Commission reiterates its recommendation that the Department of Health and Human Services should issue a statement clarifying the federal policies on prisoners' access to clinical trials and investigational new drugs. In addition, FDA, in conjunction with HRSA and NIH, should initiate an educational program directed toward informing inmates and health care professionals working in correctional facilities of the availability of investigational new drugs, expanded access programs, and applicable criteria for eligibility of prisoners in prophylactic and therapeutic research protocols.

### WHO SHOULD PAY?

The question of who pays or who should pay for experimental drugs and treatments is still a topic of considerable debate. Many people with HIV disease have significant limitations on their private and public health insurance coverage, if they have insurance at all. These limitations are typically more severe in the coverage of experimental drugs. As new proposals to expand access to experimental drugs are developed, the debate over who should pay is sure to continue to force the government and private sector to answer this question.

Traditionally, third-party payers have required evidence of a drug's safety and efficacy before routinely providing coverage, often explicitly denying coverage for experimental treatments. Such an approach has a profound impact on people with HIV disease, for whom experimental treatments are frequently the only recourse.

Third-party payers rely on a few specific sources for coverage decisions: FDA approval for drugs under treatment INDs, National Cancer Institute approval of Group C cancer drugs, or a few authoritative medical compendia (three are specifically cited in the Medicare Catastrophic Coverage Act of 1988). Relying only on such sources will greatly restrict the coverage of many potentially useful drugs, as specific approvals are sometimes not sought by the manufacturer; for some drugs and some uses approval may never be sought.

In most cases thus far, expanded access drugs for treating HIV disease have been provided by pharmaceutical companies free of charge to eligible patients, but only if patients are participating in protocols in which physicians report on the drug's effectiveness and provide the results of laboratory tests. It should be noted that, even in these special circumstances, neither the physician's time nor laboratory services are covered by the drug company.

In addition, third-party payers have often been reluctant to reimburse for so-called "off label" use of drugs, that is, use for other than indications specifically covered on the FDA-approved labeling. As treatments for HIV disease move quickly through the drug approval process, in some cases bypassing some traditional phases, the benchmarks usually relied upon by third-party payers (public and private) will have to be reconsidered. The Health Insurance Association of America, Blue Cross and Blue Shield, and HCFA are all reexamining processes for determining which experimental drugs are eligible for coverage and looking at new technology assessment procedures. This reexamination is essential for many HIV-related drugs.

The difficulties in deciding who pays for health care associated with research vividly reveals the discontinuity in federal health programs. NIH-based researchers claim no jurisdiction over health care provision, and the federal agencies responsible for the reimbursement and delivery of health care, HCFA and HRSA, are not designing program strategies that would take these research-related issues into account. As discussed above in this chapter, the Secretary of Health and Human Services should direct NIH, HCFA, and HRSA to work together to address the health care needs of clinical trial participants. This effort should include the full support and participation of the NIH Director of AIDS Research, the Administrator of HCFA, and the Administrator of HRSA.

It is important to note that the issue of who should pay the associated hospital costs when patients are taking combinations of licensed and experimental drugs is another serious problem. The NIH Reauthorization Bill that passed the House of Representatives on July 25, 1991 calls for the Department of Health and Human Services to conduct a study to determine the policies of third-party payers regarding the payments of certain health service costs that are provided as part of an individual's participation in clinical trials conducted in the development of HIV-related drugs. The Commission supports this provision and urges its swift implementation.

Access to clinical trials and experimental drugs is essential for all people with HIV disease. Access should be available equally to people in need without reference to race, ethnicity, gender, or ability to pay. The following recommendations are made with this priority in mind.

# RECOMMENDATIONS

1. Current efforts at the National Institutes of Health (NIH) to expand the recruitment of underrepresented populations in the AIDS Clinical Trials Group should be continued and increased.
   While the Commission recognizes that lack of access to health care seriously hampers efforts to recruit underrepresented people into clinical trials, this does not mean it is impossible to do so. NIH has begun to increase participation and should aggressively pursue the participation of women and people of color in their clinical trials.

2. The Secretary of Health and Human Services should direct the National Institutes of Health, the Health Care Financing Administration, and the Health Resources and Services Administration to work together to develop a series of recommendations to address the obstacles that keep many people from participating in HIV-related clinical trials, as well as the variables that force some people to seek participation in trials because they have no other health care options.

3. The Food and Drug Administration should aggressively pursue all options for permitting the early use of promising new therapies for conditions for which there is no standard therapy or for patients who have failed or are intolerant of standard therapy.

4. The National Institutes of Health should develop a formal mechanism for disseminating state-of-the-art treatment information in an expeditious and far-reaching manner.
   While the Commission is aware of the efforts at NIH to disseminate information about state-of-the-art HIV treatment, the Commission is also aware that many health care providers are still not getting the information they need to responsibly care for their patients with HIV disease. The Commission believes NIH needs to develop a more formalized mechanism for disseminating information in a timely and ongoing fashion and should work with the federally funded AIDS Education and Training Centers, as well as professional medical societies, to reach as many people as possible.

5. The Department of Health and Human Services should conduct a study to determine the policies of third-party payers regarding the payments of certain health service costs that are provided as part of an individual's participation in clinical trials conducted in the development of HIV-related drugs.

## SELECTED BIBLIOGRAPHY

AIDS Coalition to Unleash Power (ACT-UP). 1989. *A National AIDS Treatment Research Agenda.* Distributed at the Fifth Annual International Conference on AIDS, Montreal, June 4–9.

AIDS Coalition to Unleash Power (ACT-UP). 1990. *A Capsule History of ACT-UP.* New York: ACT-UP.

AIDS Treatment Registry. 1989. *Deciding to Enter an AIDS/HIV Drug Trial.* New York: AIDS Treatment Registry, Inc.

Arras, J.D. 1990. Noncompliance in AIDS research. *Hastings Center Report* 20:24–32.

Bayer, R. 1990. Beyond the burdens of protection: AIDS and the ethics of research. *Evaluation Review* 14:443–446.

Breo, D. 1991. Tired of taking the blame, AIDS drug regulator Ellen Cooper quits. *Journal of the American Medical Association* 265:1027–1028.

Byar, D.P., D.A. Schoenfeld, S.B. Green, D.A. Amato, and R. Davis. 1990. Design considerations for AIDS trials. *New England Journal of Medicine* 323:1343–1347.

Cooper, E.C. 1989. Controlled clinical trials of AIDS drugs: The best hope. *Journal of the American Medical Association* 261:2445.

Cotton, P. 1990. Is there still too much extrapolation from data on middle-aged white men? *Journal of the American Medical Association* 263:1049–1050.

Delaney, M. 1989. The case for patient access to experimental therapy. *The Journal of Infectious Diseases* 159:416–419.

Eckholm, E. 1986. Should the rules be bent in an epidemic? *New York Times.* July 13:E30.

Edgar, H., and D.J. Rothman. 1990. New rules for new drugs: The challenge of AIDS to the regulatory process. *The Milbank Quarterly* 68(Supp. 1):111–142.

Erdman, K. 1989. AIDS drugs: Is the government research program a helping hand for patients, or a handout for the pharmaceutical industry? *Public Citizen* May/June:10–13,16–17.

Freedman, B., and the McGill/Boston Research Group. 1989. Nonvalidated therapies and HIV disease. *Hastings Center Report* 19(3):14–20.

Green, S.B., S.S. Ellenberg, D. Finkelstein, A.B. Forsythe, and L.S. Freedman. 1990. Issues in the design of drug trials for AIDS. *Controlled Clinical Trials* 11:80–87.

Gross, J. 1991. Turning disease into a cause: Breast cancer follows AIDS. *New York Times.* January 7:A1.

Harrington, M., K. Fornataro and J. Eigo. 1990. *A Critique of the AIDS Clinical Trials Group.* New York: ACT-UP.

Henninger, D. 1990. Will the FDA revert to type? *Wall Street Journal.* December 12:A16.

Institute of Medicine. 1987. *An Agenda for AIDS Drug Development.* Washington, D.C.: National Academy Press.

Institute of Medicine. 1991. *The AIDS Research Program of the National Institutes of Health.* Washington, D.C.: National Academy Press.

Institute of Medicine. 1991. *Expanding Access to Investigational Therapies for HIV Infection and AIDS.* Washington, D.C.: National Academy Press.

James, J.S. 1989. *AIDS Treatment News.* Berkeley, Calif.: Celestial Arts.

Kessler, D. 1989. The regulation of investigational drugs. *New England Journal of Medicine* 320:281–288.

Kolata, G. 1988. Odd alliance would speed new drugs. *New York Times.* November 26:A9.

Lasagna, L. 1989. Congress, the FDA and new drug development: Before and after 1962. *Perspectives in Biology and Medicine* 32:322–343.

Levine, C. 1988. Has AIDS changed the ethics of human subjects research? *Law, Medicine & Health Care* 16:167–173.

Levine, C. 1990. Women and HIV/AIDS research: The barriers to equity. *Evaluation Review* 14:447–463.

Levine, R. 1988. *Ethics and Regulation of Clinical Research.* 2nd edition. New Haven, Conn.: Yale University Press.

Martin, J.M., and H.S. Sacks. 1990. Do HIV-infected children in foster care have access to clinical trials of new treatments? *AIDS & Public Policy Journal* 5:3–8.

Merigan, T.C. 1990. You *can* teach an old dog new tricks: How AIDS trials are pioneering new strategies. *New England Journal of Medicine* 323:1341–1343.

Merton, V. 1990. Community-based AIDS research. *Evaluation Review* 14:502–537.

National Committee to Review Current Procedures for Approval of New Drugs for Cancer and AIDS, President's Cancer Panel. 1990. *Final Report.* Bethesda, Md.: National Cancer Institute.

National Institute of Allergy and Infectious Diseases (NIAID). 1990. *NIAID Responds to ACT-UP Allegations and Demands.* Washington, D.C.: NIAID Office of Communications, National Institutes of Health.

National Institutes of Health. 1990. *AIDS: 1989 Research Accomplishments.* Bethesda, Md.: National Institutes of Health.

Nolan, K. 1990. AIDS and pediatric research. *Evaluation Review* 14:464–481.

Novick, A. 1989. Clinical trials with vulnerable or disrespected subjects. *AIDS and Public Policy Journal* 4:125–130.

Palca, J. 1991. Conflict over release of clinical research data. *Science* 251:374–375.

Richman, D. 1989. Public access to experimental drug therapy: AIDS raises yet another conflict between freedom of the individual and welfare of the individual and public. *Journal of Infectious Diseases* 159:412–415.

Rothman, D.J. 1987. Ethical and social issues in the development of new drugs and vaccines. *Bulletin of the New York Academy of Medicine* 63:557–568.

Rothman, D.J. 1987. Ethics and human experimentation: Henry Beecher revisited. *New England Journal of Medicine* 317:1195–1199.

Silverman, W.A. 1986. *Human Experimentation: A Guided Step into the Unknown.* New York: Oxford University Press.

Steinbrook, R., and B. Lo. 1990. Informing physicians about promising new treatments for severe illnesses. *Journal of the American Medical Association* 263:2078–2082.

U.S. Congress. House. 1988. 100th Congress, 2d Session. House Committee on Government Operations. *AIDS Drugs: Where Are They?* Report 100-1092.

Valdiserri, R.O., G.M. Tama, and M. Ho. 1988. The role of community advisory committees in clinical trials of anti-HIV agents. *IRB: A Review of Human Subjects Research* 10(4):5–7.

Vogel, D. 1989. AIDS and the politics of drug lag. *The Public Interest* 96:73–85.

Weiss, R., and L. Mazade. 1990. *Surrogate Endpoints in Evaluating the Effectiveness of Drugs Against HIV Infection and AIDS.* Washington, D.C.: National Academy Press.

James E. Smith

*From my travels and involvement with the National Association of People with AIDS, it has become painfully obvious that most of the country, if not the entire nation, does not have coordinated, collaborative, and consistent social and health care services. The tens of thousands of those of us who are infected with the human immunodeficiency virus are crying out for local, state, and national leadership. The majority of the time we feel that no one is listening, that we have been abandoned by our government and our society.*

*The HIV epidemic is much too large for national, state, and local organizations and governments to address separately or without some vehicle for coordination and direction. Our attempts during the last eight years have been incomplete, results spotty, and victories few and far between. Innovative solutions are required if our institutions are not to be brought any closer to the brink of disaster or chaos.*

JAMES SMITH
*January 1990*

## CHAPTER SIX

# GOVERNMENT RESPONSIBILITIES

The lack of a clear definition of government roles and intergovernmental partnerships has seriously hampered the nation's response to the HIV epidemic. A comprehensive national HIV plan should be developed with full participation of involved federal agencies and with input from national organizations representing various levels of government to identify priorities and resources necessary for preventing and treating HIV disease. The lack of a national plan seriously impairs efforts to end discrimination, to finance health care, to organize and deliver health and social services, to recruit and train health care workers, to provide housing for the sick, to provide effective AIDS education and prevention programs, and to provide substance use treatment. This chapter identifies government functions that are key to controlling the HIV epidemic, considers the extent to which these functions are actually fulfilled, and recommends a series of measures for improving the response of all levels of government to the HIV epidemic.

### LEADERSHIP AND PARTNERSHIP

The single most important role for government at all levels in the HIV epidemic is leadership: the ability to inspire citizens, to mobilize resources to provide for those in need, and to do so with foresight, compassion, and competence.

Appropriate government response to AIDS is a subject of enduring controversy. Elected officials at all levels of government have the responsibility to be leaders in this time of health care crisis and should exercise leadership based on sound science and informed public health practice. The Commission recognizes that many issues raised by the HIV epidemic place pressures on elected officials to pass laws intended to respond to constituent fears and concerns. The Commission, however, is very concerned that policies are being enacted into law that are better left to scientists and public health experts. Legislative action should focus on full funding of programs that provide necessary research, prevention, and treatment programs, and that protect those with HIV disease from discrimination.

The social ferment occasioned by AIDS has been great. It has risen to the top of legislative agendas; nearly one thousand bills related to AIDS were proposed in state legislatures in the first decade of the epidemic. It is the most litigated disease in American history. AIDS is also a persistent topic of headline news, although often the news centers on controversies on the periphery of the crisis—Should gay bathhouses be closed? Should children with HIV disease be excluded from school? Should health care workers be tested for HIV?—obscuring more central issues, such as the lack of access to health care and the lack of treatment opportunities for substance users.

All of this is a predictable consequence of the absence of a strong guiding voice. Committed and informed leadership is necessary to help the nation focus on the central issues that must be addressed in order to alter the course of the HIV epidemic. The waning national interest in AIDS has, on occasion, been accompanied by a backlash against sustaining levels of or commitment to funding for AIDS prevention and education, health care, and research. Some have decried what they perceive to be the privileged status of funding for AIDS research and care. But in contrast to many other diseases in society, the upsurge in AIDS deaths and illnesses is ongoing, uncontrolled, and in urgent need of further attention. The word "privileged" is especially and poignantly misused in the context of HIV disease. A diagnosis of AIDS confers no privileges; it is a frightening occurrence that severely tests physical, emotional, and economic resources.

Leadership is also essential to keeping AIDS at the top of the list of urgent national problems. The HIV epidemic will expand, demanding ever greater efforts in the years to come. It should not be allowed to fall off the list of national priorities because it seems like old news. Nor can the nation afford to indulge in exasperation or in a misapprehension that the job of prevention, care, and research is already done.

Leaders will surely have to take unpopular stands to meet the challenges posed by HIV, at least until their efforts begin to bear fruit in enhanced public understanding. Irrational fears must be allayed in order to prevent discrimination and to implement the advice of medical and public health officials. Leaders must be willing to speak on behalf of those at greatest risk of HIV disease, many of whose voices cannot be heard because they live on the margins of society.

It is important to acknowledge the differences among state, county, and municipal governments. In the case of the HIV epidemic, variations in government structure and function are complicated by major disparities in the prevalence of HIV infection. Geographic concentration of diagnosed AIDS cases was so striking a feature of the earliest phase of the epidemic that a few municipalities, counties, and states dominated both development of policy responses and consumption of resources. While the incidence of new infection has expanded far beyond these initial epicenters, the relative concentration of the epidemic in certain localities has persisted. Debates continue about how to respond to a disease that is unevenly spread throughout the country.

Government—at all levels—must do more to respond to the AIDS epidemic. The lack of government leadership in the epidemic is everywhere evident. Nevertheless, among all the tasks that must be accomplished, only some can be done by government. Even where government is not in a position to respond directly, it must still be sufficiently attentive and aggressive in assuring that a response is in place. It is imperative that government play a greater leadership role in helping to delineate responsibilities and to create effective partnerships among the various levels of government as well as with the private sector, especially insurers, foundations, corporations, and community-based organizations.

### THE PERSISTENCE OF STIGMA AND DISCRIMINATION

In some areas of the country the sheer number of people with HIV disease has forced a greater awareness and understanding of the disease and of the people living with the disease. Unfortunately HIV-related discrimination is not disappearing as more becomes known about the disease. Surveys of court cases and complaints to human rights commissions show that rather than disappearing, AIDS discrimination is changing. Subtle prejudices involving denial of basic health care services are replacing overt forms of bias.

The landmark Americans with Disabilities Act (ADA) is a significant step toward protecting the rights of all disabled Americans, including people with HIV disease. The passage of the ADA with the inclusion of protections for people with HIV disease is a victory worth celebrating. Nevertheless, it would be naive to think that such a law, in and of itself, will eliminate discrimination and injustice, any more than the civil rights legislation of 1964 has abolished discrimination based on race. Much will depend upon how assiduously the ADA is implemented and enforced. Implementation of the ADA should be carefully monitored, and states and localities should evaluate the adequacy of existing state and local antidiscrimination laws and ordinances for people with disabilities, including people living with HIV disease.

Discrimination against people with HIV disease continues to be the greatest obstacle to effectively and compassionately responding to the HIV epi-

*Timidity at the top creates tremendous burdens for the troops at the bottom.*

TIM WOLFRED
*January 1990*

demic. Even the ADA excludes active drug users, a significant portion of the people infected with HIV, from protections against discrimination. As a nation we must look carefully at all of our antidiscrimination laws and ordinances (federal, state, and local), work toward the development of additional protections where they are needed, aggressively pursue enforcement programs, and actively work to educate public and private employers, proprietors, and service providers about their lawful requirement to adhere to these laws.

### FEDERAL GOVERNMENT

While a general lack of leadership has been evident at the federal level, there have been a number of important exceptions. The early and pivotal work of the Centers for Disease Control (CDC) in epidemiologic studies to determine the modes of transmission of HIV infection was a major factor in alerting and informing the world about the epidemic. The primary role played by the National Institutes of Health (NIH) in supporting both intramural and extramural biomedical and clinical research is another example of federal leadership. NIH efforts contributed enormously to the rapid identification of the causative agent of HIV disease, the development of the HIV antibody test, and the development of drugs for treatment of HIV disease. The federal government has also played a leadership role in improving the protection of the blood and tissue supply, by accelerating procedures for testing licensure, and by production of drugs, vaccines, diagnostic reagents, and medical devices.

*I urge you as*
*a Commission to insist that*
*the President and Congress*
*reak the silence of denial and*
*peak out candidly about ways*
*to curb the spread of*
*the HIV virus and why those*
*who are infected deserve our*
*love and compassion.*

BRIAN COYLE
*January 1990*

While these successes are dramatic and noteworthy, the Commission believes that serious and substantive problems persist in the coordination of planning, policy, and program development among federal agencies. Within the Department of Health and Human Services (HHS), there is still a lack of effective coordination between the Public Health Service (PHS) and other agencies within HHS. This is particularly true between PHS, the Health Care Financing Administration, and the Social Security Administration. Reimbursement and disability issues are all crucial to the care for many people with HIV disease and should be closely linked to research, prevention, and care programs. An even greater potential for gaps exists between HHS programs and other non-health-related federal agencies. This coordination could be significantly enhanced by the adoption of a national plan for HIV including a mechanism for interdepartmental coordination within the federal government.

Although the National AIDS Program Office is designated as the coordinating agency for HIV within PHS and reports to the Assistant Secretary for Health, there is no cabinet-level coordinating group to deal with HIV, nor has a single agency been designated with the responsibility for AIDS programs. One glaring example of the absence of coordination serves to illustrate the need for improved cabinet-level communication and cooperation—the longstanding impasse over policy regarding restrictions on the travel and immigration of HIV-infected individuals. This impasse arose because of an infrequently used relationship between HHS and the Department of Justice, and in particular, because of the unwillingness of the Department of Justice to defer to HHS officials on matters of public health.

The Commission is aware that there are a number of federal HIV coordinating groups at this time and that PHS is currently finishing a strategic plan for HIV policies and programs. There is a leadership group within PHS to resolve HIV-related policy issues; there is a PHS Executive Task Force on AIDS; and there is a federal coordinating committee that includes federal agency heads.

Unfortunately, the coordinating groups as constituted do not have the breadth or the authority needed to meet the challenge of HIV disease. When coordination does take place it is most likely to occur among health-related agencies (especially within PHS). Yet non-health-related HIV issues arise with sufficient frequency to warrant more inclusive coordinating bodies. Such issues include housing, immigration, criminal justice, and corrections. Some mechanism is needed that would support ongoing consultations among all federal departments, such as the Department of Housing and Urban Development, the Department of Justice, the Department of State, and other departments and agencies that deal with AIDS-related policy issues. This coordination must also take place at the highest level of each department. Although it is important for agency staff members to meet regularly to cement working relationships, it is also critical that cabinet secretaries themselves forge the broad policy outlines.

### Technical Assistance and Evaluation

State and local governments need a much broader form of technical assistance from the federal government than is currently envisioned or provided by any one agency. Usually, assistance does not extend through the life of a program; it is narrowly confined to the particular program and is primarily attuned to the needs of the granting agency.

To some extent, a model for a broader form of technical assistance or capacity building existed during the 1970s in the CDC regional centers for training and technical assistance in the areas of sexually transmitted diseases and tuberculosis. Although HIV technical assistance would have to span an even broader range of programs and agencies, the defining characteristics of such centers could be usefully applied. Staff at these centers were permanently assigned to fostering

early one
thousand bills
related to AIDS
were proposed in
state legislatures
in the first decade
of the epidemic.
It is the most
litigated disease in
American history.

> *Too often we are denied services or cannot find services that adequately address the real needs in our lives because of gender issues, economic issues, politics, racism, sexism, and because we do not yet have a single strong voice of advocacy. We are so preoccupied with meeting the needs of others that there is never enough attention focused on our own needs. Many of us are poor and must improvise and compromise ourselves or simply do without much needed support, basic services, love and attention, and all of the simple things in life which help people develop whole and wholesome attitudes about themselves.*
>
> JANICE JIREAU
> *June 1991*

state and local competence and were able to assist state and local governments in evaluating and developing policies and programs, in training staff, and in planning for future needs. Support of this kind would require a substantial change in the way federal agencies do business—in effect, it would require the creation of field technical assistance teams not tied to specific federal programs or funding streams.

A related but separate need exists for technical assistance and capacity building for community-based organizations. Such assistance would include financial management, personnel recruitment and management, program planning, and evaluation systems, as well as program and policy issues more directly related to HIV prevention and treatment.

A fundamental and persistent problem in the development of policies and programs at all levels of government has been the lack of adequate evaluation. Even now, a decade into the epidemic, new programs continue to be introduced with inadequate evaluation designs and processes. Without such evaluations the ability to discern useful strategies is lost, and continued funding of effective public programs may well be jeopardized through lack of supporting data and documentation.

One critical factor contributing to the failure to evaluate public programs has been a marked degree of confusion about which level of government, and which agency at each level, is responsible for evaluation. Clear decisions are needed concerning which agency requires the evaluation, which provides technical assistance, who funds it, and who ensures that it is done and renders the results both accessible and understandable. Outside observers often criticize program administrators for failing to evaluate their own programs when in fact operating agencies rarely have the funds or technical assistance required to make such analyses. This could be addressed by increased funding for evaluation and by a concentrated federal effort to develop and provide technical assistance in the specific area of evaluation.

Often funds for technical assistance and evaluation are included in administrative budgets for public programs. This almost invariably results in inadequate support, both in absolute terms and as a proportion of program funds. Reasons given for this include legislative concern over the propriety of large administrative budgets and limited support for appropriating money to state and local government for evaluation and technical assistance. This has been the case particularly when federal dollars have been limited and when a choice had to be made between putting the money into the actual delivery of services or into administration.

State and local governments have a substantial need for technical assistance, evaluation, and program dollars. These activities should not be forced to compete with each other. For example, full funding of the Ryan White CARE Act is required to meet both the operational and administrative needs of CARE Act programs. There is a critical need for more broad-based technical assistance and capacity building in all HIV-related programs. In addition, ways must be found to ensure that new programs are responsive to local needs.

There is also a notable lack of agencywide guidance for program evaluation within CDC, the Health Resources and Services Administration (HRSA), the National Institute on Drug Abuse, and other PHS agencies. Such leadership should emphasize the short-term development of information that will be useful in further policy planning and in program design and implementation. Evaluation plans are most objective and useful when they are developed before programs are implemented; but unfortunately at present they are almost exclusively designed and instituted after programs have been implemented. This results in unnecessary complexity, undue delay, and greater costs than the information produced would warrant. Finally, to warrant investment in them, evaluations must be synthesized and disseminated in a manner useful to state and local agencies.

### Coordination

As noted above, federal HIV-related programs are housed in a number of federal agencies, without a coordinating body or lead agency to track and resolve contradictory and overlapping program elements. States and localities are left to cope with funding and administrative requirements that expand their own bureaucracies and limit their flexibility.

With the implementation of the CARE Act have come some improvements in interagency coordination within PHS, particularly between HRSA and CDC. Neither Congress nor federal agencies are preparing adequately, however, for the growing discrepancy between available resources and caseloads of HIV-infected persons. Plans should be undertaken with a sense of urgency to make changes in policies, structures, functions, and uses of public monies to cope with dramatic expansion of needs. Plans must also be made to cope with shifts and evolutions in relationships between government and private partners.

The necessity of planning cannot be overemphasized. It is all the more pressing in light of the critical budget

> *Most of the key transactions that affect the health of people take place in households, in neighborhoods, in communities. So finally, those of us at the federal level are two steps removed, and even state health officials are one step removed from where things really happen at the community level. I believe that the most important thing I can do as a federal official is to work to strengthen local public health agencies across the country.*
>
> WILLIAM ROPER, M.D., M.P.H.
> *September 1990*

deficits at federal, state, and local levels (which are at their worst in some of the states with the highest prevalence of HIV disease). Research on the cost-effectiveness of alternative policies and programs should be a key component of this planning process.

### Limitations of Research and Demonstration Programs

Federal, state, and local agencies have frequently found themselves resorting, de facto, to the use of research funds to pay for outreach and health care delivery services. This occurs because of a high level of need for direct services and insufficient funds to meet that need. Sometimes programs begin as demonstration projects for services and are "retrofitted" as research studies. Under such circumstances services are in serious jeopardy if and when the demonstration has been judged successful and the research is concluded. Often the research agencies that funded the projects initially argue that they are not authorized to continue service delivery beyond the specific demonstration programs. Thus there may be an abrupt cessation of care for desperately ill people. Further, the services themselves are "cadillac models" developed with research funds and are sometimes too expensive to implement on a larger scale. Yet dependent populations and political constituencies understandably may protest the significant curtailment of care.

> *What I'd like to do is try to bring to you the perspective of the local health officer and the local health department as we have responded to the HIV epidemic. It is not an easy task because the response has been very diverse locally. It has been diverse due to different resources, due to different attitudes in the communities, and certainly due to different traditions in the communities and different support among the political leadership of the local communities.*
>
> WILLIAM MYERS, M.S.
> *September 1990*

### STATE GOVERNMENT

Many states have organized comprehensive planning processes or have worked extensively with health care providers, employers, volunteer groups, and others in the development of policies for HIV prevention and treatment. Nevertheless, problems of coordination among state agencies are common. These problems have been exacerbated by the rapid growth of HIV programs and by the fact that staff in agencies other than public health departments are often unfamiliar with HIV-related issues. These problems become even more critical in light of state deficits, as states may be forced into uncoordinated and even contradictory policies in response to federal funding streams.

These difficulties have existed since the onset of the epidemic. As noted above, recent budget deficits have developed in many areas with moderate-to-high HIV prevalence rates. The pressures of these deficits are likely to erode existing programs and to leave states, counties, and municipalities unable to meet the rising tide of need for HIV services. The same financial crises may also make it all but impossible for these localities to comply with or fulfill the intent of federal programs when maintenance of level-of-effort or matching funds are required.

### LOCAL GOVERNMENT COUNTY AND MUNICIPAL

A number of examples of extraordinary leadership on the local level have emerged in recent years. Many county and municipal governments have established comprehensive planning processes that involve not only health care providers and public health leaders, but also a much broader base of citizens, HIV-infected individuals, and representatives of impacted communities. Also, many counties and municipalities have worked successfully with employers to sponsor policies against discrimination and to educate employers, health care providers, community and religious organizations, and other public sector agencies including police, emergency services, and schools.

The capacities of some county and municipal governments are strained, however, by jurisdictions too small to support adequate county and municipal health departments. These small counties and cities operate without the public health programs and competence necessary to organize effective HIV-related (or other) public health and medical programs.

County and municipal governments are increasingly overwhelmed by the demands of providing access to medical care services (HIV-related and non-HIV-related). Although local government is the provider of last resort for a growing population of medically indigent people, tax revenues are diminishing in proportion to the programs now delegated to local government, and access to care must compete with many other important social programs including education, public safety, and general assistance.

Lack of information and technical assistance is as critical a problem at the local level as it is for state agencies. State and federal agencies provide no systematic information or technical assistance regarding HIV program design, management, and effectiveness.

All levels of government must exhibit strong leadership and improve their response to the HIV epidemic. The following recommendations should be adopted immediately.

# RECOMMENDATIONS

1. **A comprehensive national HIV plan should be developed with the full participation of involved federal agencies and with input from national organizations representing various levels of government to identify priorities and resources necessary for preventing and treating HIV disease.**

   To develop the comprehensive national HIV plan, the Commission calls upon the President of the United States to designate an individual or lead agency with the authority and responsibility for instituting a cabinet-level process to articulate the federal component of an HIV plan, develop a mechanism for interagency as well as state and local participation and coordination, and establish a timeline for completion of key tasks.

2. **All levels of government should develop comprehensive HIV plans that establish priorities, ensure consistent and comprehensive policies, and allocate resources.**

   These plans should build on the national HIV plan and be developed at the state level with clear direction and support from each governor and at the appropriate local level (city or county) with clear direction and support from the appropriate locally elected official body. Each level of government should have an HIV Advisory Committee that is composed of representatives of diverse community-based organizations; the private sector; religious organizations; public safety officials; people living with AIDS; housing, health, and social service agencies; and other appropriate representatives.

   The Commission recognizes that most states and many local governments may have an HIV plan. However, these existing plans should be carefully reviewed to ensure that they are up to date and comprehensive, and that they coordinate the entire spectrum of prevention and treatment services.

3. **Implementation of the Americans with Disabilities Act should be carefully monitored, and states and localities should evaluate the adequacy of existing state and local antidiscrimination laws and ordinances for people with disabilities, including people living with HIV disease.**

4. **Elected officials at all levels of government have the responsibility to be leaders in this time of health care crisis and should exercise leadership in the HIV epidemic based on sound science and informed public health practices.**

   The Commission recognizes that many issues raised by the HIV epidemic place pressures on elected officials to pass laws intended to respond to constituent fears and concerns. The Commission, however, is very concerned that policies may be enacted into law that are better left to scientists and public health experts. Legislative focus should be on full funding of HIV-related research, prevention, and treatment programs and on protecting those with HIV disease from discrimination.

5. **The federal government should develop an evaluation and technical assistance component for all federally funded HIV-related programs.**
   Understanding what works and why is essential to the development of effective prevention and care services for people living with HIV disease. It is essential that all HIV-related prevention and treatment efforts be evaluated and that the information be integrated into all planning, prevention, and health care delivery programs.

## SELECTED BIBLIOGRAPHY

Abt, C.C., and K.M. Hardy, eds. 1990. *AIDS and the Courts.* Cambridge, Mass.: Abt Books Inc.

American Bar Association (ABA). 1989. *Policy on AIDS and the Criminal Justice System.* Resolution Adopted by the House of Delegates. Chicago, Ill.: American Bar Association.

American Bar Association (ABA). 1990. *Policy on AIDS.* Chicago, Ill.: American Bar Association.

Annas, G.J. 1991. Back to the future: The IOM report reconsidered. *American Journal of Public Health* 81:835–837.

Association of State and Territorial Health Officials (ASTHO). 1987. *Guide to Public Health Practice: AIDS Confidentiality and Anti-Discrimination Principles: Interim Report.* Washington, DC.: Association of State and Territorial Health Officials.

Brandt, A. 1985. *No Magic Bullet: A Social History of Venereal Disease in the United States Since 1880.* New York: Oxford University Press.

Cunningham, I. 1989. The public controversies of AIDS in Puerto Rico. *Social Science and Medicine* 29:545–553.

Dalton H.L., S. Burris, and the Yale AIDS Law Project, eds. 1987. *AIDS and the Law.* New Haven, Conn.: Yale University Press.

Gostin, L.O. 1989. The politics of AIDS: Compulsory state powers, public health, and civil liberties. *Ohio State Law Journal* 49:1017–1058.

Gostin, L.O. 1989. Public health strategies for confronting AIDS: Legislative and regulatory policy in the United States. *Journal of the American Medical Association* 261:1621–1630.

Gostin, L.O., ed. 1990. *AIDS and the Health Care System.* New Haven, Conn.: Yale University Press.

Gostin, L.O. 1990. The AIDS litigation project: A national review of court and human rights commission decisions. Part II. Discrimination in education, employment, housing, insurance and health care. *Journal of the American Medical Association* 263:2086–2093.

Gostin, L.O., L. Porter, and H. Sandomire. 1990. *U.S. AIDS Litigation Project: A National Survey of Federal, State and Local Cases Before Courts & Human Rights Commissions.* Volume I. Contract with the Office of the Assistant Secretary of Health, Department of Health and Human Services. Washington, D.C.: U.S. Government Printing Office.

Gostin, L.O., L. Porter, and H. Sandomire. 1990. *U.S. AIDS Litigation Project: Objective Description of Trends in AIDS Litigation.* Volume II. Contract with the Office of the Assistant Secretary of Health, Department of Health and Human Services. Washington, D.C.: U.S. Government Printing Office.

Hunter, N. 1990. *Epidemic of Fear—A Survey of AIDS Discrimination in the 1980's and Policy Recommendations for the 1990's.* New York: American Civil Liberties Union AIDS Project.

Institute of Medicine. 1988. *Confronting AIDS: Directions for Public Health and Research.* Washington, D.C.: National Academy Press.

Institute of Medicine. 1989. *The Future of Public Health.* Washington, D.C.: National Academy Press.

Intergovernmental Health Policy Project AIDS Policy Center. 1989. *Policy Maker's Guide on AIDS.* Washington, D.C.: Intergovernmental Health Policy Project.

Intergovernmental Health Policy Project AIDS Policy Center. 1989. *State AIDS Legislation Related to Worker Notification and Exposure: 1983–88.* Washington, D.C.: Intergovernmental Health Policy Project.

Intergovernmental Health Policy Project AIDS Policy Center. 1989. *State Laws Governing Confidentiality of HIV-Related Information.* Washington, D.C.: Intergovernmental Health Policy Project.

Intergovernmental Health Policy Project AIDS Policy Center. 1991. *A Summary of HIV/AIDS Laws From the 1990 State Legislative Sessions.* Washington, D.C.: Intergovernmental Health Policy Project.

National Association of Counties Task Force on HIV Infection and AIDS. 1989. *County Government and HIV Infection.* Washington, D.C.: National Association of Counties

Panem, S. 1988. *The AIDS Bureaucracy.* Cambridge, Mass.: Harvard University Press.

Parmet, W. 1990. Discrimination and disability: The challenges of the ADA. *Law, Medicine & Health Care* 18:331–344.

Rowe, M., and C. Ryan. 1989. *A Governor's Policy Guide on AIDS.* Washington, D.C.: National Governor's Association.

Stoddard, T.B., and W. Rieman. 1990. AIDS and the rights of the individual: Toward a more sophisticated understanding of discrimination. *Milbank Quarterly* 68:143–174.

United States Conference of Mayors. 1991. *The Impact of AIDS on America's Cities.* Washington, D.C.: United States Conference of Mayors.

# CONCLUSION

Over the past two years the National Commission on AIDS has called for federal leadership in the HIV epidemic and for the creation of partnerships at all levels of government and in the private sector. We have also emphasized the need to develop and assure access to a system of health care for all people with HIV disease. The fundamental right of all people with HIV disease to be protected against discrimination has guided all of our work. We have conducted numerous hearings and site visits, heard from nearly one thousand people across the country, and have issued a series of interim reports designed to focus on topics that we thought were particularly important and urgent to bring to the attention of the President and Congress. This report is intended to underscore the importance of all of these efforts, as well as linking HIV prevention, care, treatment, and research, and improving the coordination of all of the mechanisms designed to pay for these programs.

In the coming year, the National Commission on AIDS will continue to bring urgent matters to the attention of the President and the Congress; to monitor the adoption and implementation of the recommendations contained in this report; to seek to build a broad public understanding on the magnitude, scope, and urgency of the HIV epidemic; to provide and inspire leadership at all levels of both public and private sectors; and to advocate for effective, cooperative, and nondiscriminatory systems and resources required for the prevention, comprehensive care and treatment, and research necessary to halt the epidemic.

There is still much to do. The National Commission on AIDS calls on all of our nation's leaders to enter into partnership with us to work with the individuals and communities throughout the United States who have for too long felt forgotten or abandoned by their government.

# CUMULATIVE RECOMMENDATIONS

## PREVENTION AND EDUCATION

1. **The federal government should establish a comprehensive national HIV prevention initiative.**
   This initiative should be authorized by Congress and developed by the Department of Health and Human Services. It should provide flexible resources to state and local government and other public or private nonprofit entities for communitywide HIV prevention efforts. It must also include input from individuals who have expertise through experience, education, or training. The prevention initiative is an essential component of a national HIV plan.

2. **Greater priority and funding should be given to behavioral, social science, and health services research.**
   Behavioral, social science, and health services research are currently grossly underfunded. The Commission believes there must be a more appropriate balance of funding between these areas of study and biomedical research.

3. **Congress should remove the government restrictions that have been imposed on the use of funds for certain kinds of HIV education, services, and research.**
   Government restrictions on certain HIV programs and on behavior-oriented research studies impede the fight against HIV disease. HIV prevention programs and research into sexual and drug using behaviors must be conducted and evaluated. Results from these and other health promotion and disease prevention efforts must be shared and rapidly incorporated into HIV prevention and education strategies.

4. **The U.S. Public Health Service should expand and promote comprehensive programs for technical assistance and capacity building for effective long-term prevention efforts.**

5. **Federal, state, and local governments should join forces with the private sector in providing long-term support to community-based organizations.**
   Community-based efforts are now and will continue to be an integral part of any HIV prevention strategy. The role of people with HIV disease must be recognized,

encouraged, and supported. In designing services, community-based organizations and their programs must be accountable, yet they must be afforded sufficient flexibility to implement programs that will best serve communities in need.

6. Policies should be developed now to address future plans for the distribution of AIDS vaccines and the ethical and liability issues that will arise when vaccines become available.

7. The federal government should expand drug abuse treatment so that all who apply for treatment can be accepted into treatment programs. The federal government should also continually work to improve the quality and effectiveness of drug abuse treatment.

8. Legal barriers to the purchase and possession of injection equipment should be removed.
   Legal barriers do not reduce illicit drug injection. They do, however, limit the availability of new, clean injection equipment, thereby encouraging the sharing of injection equipment, and the increase in HIV transmission.

## CARING FOR PEOPLE WITH HIV DISEASE

1. Government should assure access to a system of health care for all people with HIV disease.
   At a minimum, a system of care for all people with HIV disease should include a package of continuous and comprehensive medical and social services designed to enhance quality of life and minimize hospital-based care. States, counties, and municipalities should assure that such services are available for individuals with HIV disease. Case management programs should be available to coordinate such care. These services must include:
   - HIV antibody testing that is voluntary and must be accompanied by counseling—both anonymous and confidential testing contribute in different ways and both options should be available;
   - education and counseling to help foster and maintain behavioral changes to reduce transmission of the virus;
   - medical care, including drug therapy and frequent diagnostic monitoring, ongoing primary care, coordination of inpatient and outpatient care, access to investigational new therapies, and adequate options for long-term care;
   - psychological care, including mental health counseling and spiritual support, that is helpful in coping with a frightening and sometimes overwhelming condition;

- drug treatment to help individuals stop using or injecting drugs or adopt safer drug use practices; and
- social services, including a range of housing options and income maintenance, without which medical advances may be beyond the grasp of those who could most benefit from them.

2. HIV-related services should be expanded to facilities where underserved populations receive health care and human services, in part to ensure their increased participation in trials of investigational new therapies.

3. HIV education and training programs for health care providers should be improved and expanded, and better methods should be developed to disseminate state-of-the-art clinical information about HIV disease, as well as drug and alcohol use, to the full range of health care providers.

   The Commission believes all health care providers have an ethical responsibility to care for people with HIV disease. In order to equip providers to better counsel and care for people with HIV disease, government at all levels and local agencies and institutions must develop more effective education programs and methods for getting the information to all providers, particularly primary care providers.

   Programs to train health care providers to recognize and manage drug and alcohol use must be expanded, and programs that integrate treatment of drug use with primary care must be created and supported. The Commission believes more federal funds are needed for these efforts.

4. Federal, state, and local entities should provide support for training, technical assistance, supervisory staff, and program coordination to acknowledge and support the family members, friends, and volunteers who are an integral part of the care system of a person with HIV disease.

## HEALTH CARE FINANCING

1. Universal health care coverage should be provided for all persons living in the United States to ensure access to quality health care services.

   The Commission believes universal health care coverage is a necessary step to ensuring access to quality health care. This coverage should be comprehensive and should include prescription drugs. In the interim, the Commission recommends a series of immediate short-term steps to address the urgent problem of inadequate coverage for people with HIV disease.

2. **Medicaid should cover all low-income people with HIV disease.**
   The Commission recommends eliminating the disability requirement and raising the income level for Medicaid eligibility for people with HIV disease. By eliminating the disability requirement, low-income people with HIV infection who have not had a clinical diagnosis of AIDS could be covered by Medicaid and receive the early intervention treatments and services they need. Increasing the income eligibility requirement would prevent many people with HIV infection from having to impoverish themselves in order to qualify for basic health care services. At the same time it would relieve some of the reliance on public hospitals by the uninsured.

   The Commission strongly believes these changes should be mandated; however, at the very least, states should be given the option of making these changes. In addition, the Commission believes these changes can and should lead to further changes that will include people with serious chronic conditions other than HIV disease.

3. **Medicaid payment rates for providers should be increased sufficiently to ensure adequate participation in the Medicaid program.**
   Unrealistically low reimbursement rates under the Medicaid program serve as a serious disincentive for health care providers to care for people who rely on Medicaid. Medicaid rates should be raised to Medicare levels.

4. **Congress and the Administration should work together to adequately raise the Medicaid cap on funds directed to the Commonwealth of Puerto Rico to ensure equal access to care and treatment.**
   Because of the existing cap on Medicaid funds allocated to the Commonwealth of Puerto Rico, none of the Medicaid recommendations the Commission has put forward to expand benefits for people with HIV disease would include individuals living in this part of the United States.

5. **States and/or the federal government should pay the COBRA premiums for low-income people with HIV disease who have left their jobs and cannot afford to pay the health insurance premium.**

6. **Social Security Disability Insurance (SSDI) beneficiaries who are disabled and have HIV disease or another serious chronic health condition should have the option of purchasing Medicare during the current two-year waiting period.**
   Medicaid should be required to purchase Medicare coverage for low-income SSDI beneficiaries.

7. **The federal government should fund the Ryan White CARE Act at the fully authorized level.**

8. The following interim steps to improve access to expensive HIV-related drugs should be taken:
    (a) adequately reimburse for the purchase of drugs required in the prevention and treatment of HIV disease, including clotting factor for hemophilia;
    (b) undertake, through the Department of Health and Human Services, a consolidated purchase and distribution of drugs used in the prevention and treatment of HIV disease;
    (c) amend the Orphan Drug Act to set a maximum sales cap for covered drugs.

## CLINICAL TRIALS AND TREATMENT-RELATED RESEARCH

1. Current efforts at the National Institutes of Health (NIH) to expand the recruitment of underrepresented populations in the AIDS Clinical Trials Group should be continued and increased.

    While the Commission recognizes that lack of access to health care seriously hampers efforts to recruit underrepresented people into clinical trials, this does not mean it is impossible to do so. NIH has begun to increase participation and should aggressively pursue the participation of women and people of color in their clinical trials.

2. The Secretary of Health and Human Services should direct the National Institutes of Health, the Health Care Financing Administration, and the Health Resources and Services Administration to work together to develop a series of recommendations to address the obstacles that keep many people from participating in HIV-related clinical trials, as well as the variables that force some people to seek participation in trials because they have no other health care options.

3. The Food and Drug Administration should aggressively pursue all options for permitting the early use of promising new therapies for conditions for which there is no standard therapy or for patients who have failed or are intolerant of standard therapy.

4. The National Institutes of Health should develop a formal mechanism for disseminating state-of-the-art treatment information in an expeditious and far-reaching manner.

    While the Commission is aware of the efforts at NIH to disseminate information about state-of-the-art HIV treatment, the Commission is also aware that many health care providers are still not getting the information they need to responsibly care for their patients with HIV disease. The Commission believes NIH needs to develop a more formalized mechanism for disseminating information in a timely and ongoing fashion and should work with the federally funded AIDS Education and Training Centers, as well as professional medical societies, to reach as many people as possible.

5. The Department of Health and Human Services should conduct a study to determine the policies of third-party payers regarding the payments of certain health service costs that are provided as part of an individual's participation in clinical trials conducted in the development of HIV-related drugs.

## GOVERNMENT RESPONSIBILITIES

1. A comprehensive national HIV plan should be developed with the full participation of involved federal agencies and with input from national organizations representing various levels of government to identify priorities and resources necessary for preventing and treating HIV disease.

   To develop the comprehensive national HIV plan, the Commission calls upon the President of the United States to designate an individual or lead agency with the authority and responsibility for instituting a cabinet-level process to articulate the federal component of an HIV plan, develop a mechanism for interagency as well as state and local participation and coordination, and establish a timeline for completion of key tasks.

2. All levels of government should develop comprehensive HIV plans that establish priorities, ensure consistent and comprehensive policies, and allocate resources.

   These plans should build on the national HIV plan and be developed at the state level with clear direction and support from each governor and at the appropriate local level (city or county) with clear direction and support from the appropriate locally elected official body. Each level of government should have an HIV Advisory Committee that is composed of representatives of diverse community-based organizations; the private sector; religious organizations; public safety officials; people living with AIDS; housing, health, and social service agencies; and other appropriate representatives.

   The Commission recognizes that most states and many local governments may have an HIV plan. However, these existing plans should be carefully reviewed to ensure that they are up to date and comprehensive, and that they coordinate the entire spectrum of prevention and treatment services.

3. Implementation of the Americans with Disabilities Act should be carefully monitored, and states and localities should evaluate the adequacy of existing state and local antidiscrimination laws and ordinances for people with disabilities, including people living with HIV disease.

4. Elected officials at all levels of government have the responsibility to be leaders in this time of health care crisis and should exercise leadership in the HIV epidemic based on sound science and informed public health practices.
   The Commission recognizes that many issues raised by the HIV epidemic place pressures on elected officials to pass laws intended to respond to constituent fears and concerns. The Commission, however, is very concerned that policies may be enacted into law that are better left to scientists and public health experts. Legislative focus should be on full funding of HIV-related research, prevention, and treatment programs and on protecting those with HIV disease from discrimination.

5. The federal government should develop an evaluation and technical assistance component for all federally funded HIV-related programs.
   Understanding what works and why is essential to the development of effective prevention and care services for people living with HIV disease. It is essential that all HIV-related prevention and treatment efforts be evaluated and that the information be integrated into all planning, prevention, and health care delivery programs.

# APPENDIXES

## APPENDIX A

## COMMISSION CHRONOLOGY 1989–1993

1989

| | |
|---|---|
| August 3 | Meeting to select Chairman and discuss future direction of Commission. Washington, D.C. |
| August 17 | Meeting to select Executive Director. Washington, D.C. |
| September 6 | Statement in support of passage of the Americans with Disabilities Act. |
| September 18–19 | Hearings to gain an overview of the HIV epidemic. Washington, D.C. |
| September 19 | Statement in support of increase in AIDS funding in the FY'90 Appropriations Bill. |
| September 26 | Statement in support of the goal of treatment on demand for drug users. |
| November 2–3 | Hearings on health care, treatment, finance, and international aspects of the HIV epidemic. Washington, D.C. |
| November 7 | Statement in support of continued funding of research on the effectiveness of bleach distribution. |
| December 5 | First interim report to President Bush and the Congress: "Failure of U.S. Health Care System to Deal with HIV Epidemic." |
| December 12 | Press conference in which a Commission resolution calls for an end to discriminatory visa and immigration practices and a review of immigration policies regarding communicable diseases, particularly HIV infection. Washington, D.C. |

1990

| | |
|---|---|
| January 4–5 | Hearing of the Working Group on Federal, State, and Local Responsibilities. Purpose was to examine the roles and responsibilities of different levels of government in responding to the AIDS/HIV epidemic. St. Paul, Minnesota. |
| January 24–26 | Hearing and site visits to assess regional aspects of the HIV epidemic in Southern California. Visits were made to Los Angeles Area community-based organizations, clinics, a hospice, and a public hospital. Los Angeles, California. |
| February 15–16 | Hearing of the Working Group on Social and Human Issues. Purpose was to examine the relationship of early intervention, HIV testing, and psychosocial issues to HIV. Boston, Massachusetts. |
| February 26–27 | Site visits to study issues of HIV and AIDS among the homeless, drug users, and hemophiliacs. New York City, Newark, and Jersey City. |
| March 6 | Testimony of Chairman June E. Osborn, M.D., on meeting the health care needs of people living with HIV and AIDS before the Task Force on Human Resources of the Committee of the Budget of the United States House of Representatives. |
| March 6 | Statement endorsing principles and objectives of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990. |
| March 9 | Letter to President Bush urging him to resolve visa controversy before international conferences to be held in the United States in June and August of 1990. |
| March 15 | Statement that despite debate among epidemiologists, HIV epidemic will have a greater impact in the 1990s than in the 1980s. |
| March 15 | Summary Report of the Working Group on Federal, State, and Local Responsibilities, including recommendations from January meeting in St. Paul, Minnesota, on the roles and responsibilites of different levels of government. |
| March 15–16 | Hearings to review executive and legislative branch initiatives, including the National Drug Control Strategy and the Report of the U.S. Bipartisan Commission on Comprehensive Health Care. Washington, D.C. |
| April 16–17 | Site visits to examine issues surrounding AIDS in rural communities. Waycross, Albany, and Macon, Georgia. |
| April 24 | Second interim report to President Bush and the Congress: "Leadership, Legislation, and Regulation." |
| May 7 | Letters to Senate Majority Leader Mitchell and Senate Minority Leader Dole urging Senate consideration of the Ryan White CARE Act of 1990. |
| May 7–8 | Hearings to review current research activities, particularly clinical trials. Washington, D.C. |
| May 11 | Statement endorsing principles and objectives of AIDS Prevention Act (H.R. 4470) and Medicaid AIDS and HIV Amendments Act of 1990 (H.R. 4080). |

| | |
|---|---|
| May 24 | Letters to Senators Kennedy and Hatch underscoring support for the Americans with Disabilities Act and declaring the amendment concerning food handlers bad public health policy. |
| June 6 | Letters to Speaker of the House Foley and House Minority Leader Michel urging Congress to resist attempts to impose a federal mandate on states for name reporting. |
| June 27 | Testimony of Commissioner Donald S. Goldman before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce of the United States House of Representatives regarding immigration and visa policies and the Rowland Bill (H.R. 4506). |
| July 9–10 | Hearing by the Working Group on Social and Human Issues to examine early intervention and HIV testing from the public health perspective, as well as the range of social and human services needed by people affected by the HIV/AIDS epidemic. Dallas, Texas. |
| July 17–19 | Hearings to review current health care personnel and work force issues. Washington, D.C. |
| July 30–31 | Working Group on Social and Human Issues hearing and site visits to examine the range of services needed by people affected by the HIV/AIDS epidemic, the partnerships and coalitions necessary to provide these services, and the social and human services programs established in the Seattle-King County Region. Seattle, Washington. |
| August 16–17 | Hearings and site visits to examine HIV infection and AIDS in correctional facilities. New York State. |
| August 21 | Third interim report to President Bush and the Congress: "Research, the Work Force, and the HIV Epidemic in Rural America." |
| August | First Annual Report to the President and the Congress documenting and describing the work of the Commission over the past year. |
| September 17–18 | Hearings on public health and the HIV epidemic. Washington, D.C. |
| September 18 | Letter to President Bush and Members of Congress calling for full funding of the Ryan White CARE Act. |
| November 27–28 | Hearings and site visits to assess the impact of the HIV epidemic in the Commonwealth of Puerto Rico. San Juan, Puerto Rico. |
| December 17–18 | Hearings on HIV disease in African-American communities. Baltimore, Maryland. |

1991

| | |
|---|---|
| January 16–17 | Hearings on HIV disease and substance use. Washington, D.C. |
| February 6–7 | Site visits to examine regional response to the HIV epidemic. Belle Glade and Miami, Florida. |
| February 15 | Letter to Charles McCance, Director of Quarantine, Centers for Disease Control, regarding the immigration issue. |
| February 25–28 | Site visits to study HIV disease in Native American communities. Oklahoma, Minnesota, South Dakota, Arizona, and New Mexico. |
| March 6 | Statement endorsing the principles and objectives of the Ryan White CARE Act. |
| March 11–13 | Hearings and site visits to assess pediatric and adolescent HIV disease and AIDS/HIV in Hispanic communities. Chicago, Illinois. |
| March 15 | Fourth interim report to President Bush and the Congress: "HIV Disease in Correctional Facilities." |
| March 21 | Testimony of Chairman June E. Osborn, M.D., before the Senate Appropriations Committee. |
| April | Report of the Working Group on Social and Human Issues. |
| April 22–23 | Hearings and meeting on financing, the federal structure, and consultants' reports for the Second Annual Commission Report. Washington, D.C. |
| April 30 | Testimony of Chairman June E. Osborn, M.D., before the House Appropriations Committee. |
| May 16–17 | Hearings on the HIV epidemic in the lesbian, gay, and bisexual communities and on HIV disease among Asians, Asian-Americans, and Pacific Islanders. San Francisco, California. |
| June 5 | Letter to Members of Congress regarding funding of the Ryan White CARE Act. |
| June 5–7 | Hearings and meeting on women and HIV disease, civil rights and HIV disease, and the Second Annual Commission Report. Denver, Colorado. |
| June 10–11 | Meeting to discuss the Second Annual Commission Report. Alexandria, Virginia. |
| June 13 | Letter to Attorney General Richard Thornburgh with accompanying letter to Secretary Louis Sullivan regarding current immigration policy. |
| July 11 | Statement of the Commission's stand on HIV testing in the health care workplace. |
| July 11 | Statement of the Commission's stand on immigration. |

| | |
|---|---|
| July 24 | Letter to congressional leadership regarding support for funding of behaviorial and social research. |
| August 6 | Fifth interim report to President Bush and the Congress: "The Twin Epidemics of Substance Use and HIV." |
| September 25 | Second annual report to the President and the Congress: "America Living With AIDS." |

# APPENDIX B

## RECOMMENDATIONS FROM PREVIOUS REPORTS

### Report Number One:
### Failure of U.S. Health Care System to Deal with HIV Epidemic
### December 1989

What is Needed?

FIRST, frank recognition that a crisis situation exists in many cities that will require extraordinary measures to overcome. Significant changes must be made not only in our health care system but in how we think about the system and the people it is designed to serve. As one witness told the Commission, it can no longer be "business as usual."

SECOND, the creation of a flexible, patient-oriented, comprehensive system of care, closely linking hospital, ambulatory, residential, and home care. Primary care physicians must be central to such a system. But if primary care doctors are to care for patients with HIV infection and AIDS, they need the financial, social and institutional support to assist them in managing complicated patients.

THIRD, consideration of the creation of regional centers of networks of care, perhaps using the already existing regionalized hemophilia treatment program as a model. These centers would not serve as a replacement for the care provided by primary care physicians but would provide backup and consultation to help strengthen community based primary care.

It is essential that everyone be afforded early intervention and access to care. In addition, the availability of backup and consultation from appropriate specialists is required to provide the assistance and encouragement primary care doctors need to see more people with HIV infection and AIDS. Regional centers should also provide the appropriate link with the hospital when hospital services are needed.

FOURTH, create units which can treat patients who have both HIV infection and drug addiction. The availability of drug treatment on request is essential for responding to the combined HIV and drug epidemic that imperils not only drug users but also their sexual partners and children.

Given the massive link between drug use and HIV infection, and the fact that there is an alarming increase in the number of new infections among intravenous drug users, the Commission wishes to go on record in expressing its surprise and disappointment that the White House National Drug Control Strategy mentions AIDS only four times in its ninety pages of text and not at all in its recommendations or discussions of how to allocate resources. The President's drug strategy simply must acknowledge and include HIV infection and AIDS.

FIFTH, provide comprehensive health care services under one roof. Fragmented services create additional barriers to needed health care. Often mothers will seek health care services needed for their babies but are not able to then gain access to care for themselves. Health care services for women and children need to be provided in one place. For the homeless, housing and health care need to go hand-in-hand. This is true not only for those who are homeless today but for those who will become homeless tomorrow because of the HIV epidemic.

# Report Number Two:
# Leadership, Legislation and Regulation
## April 1990

1. The National Commission on AIDS will continue to recommend policy goals for a national plan. However, the Commission believes it is essential that a federal interagency mechanism be in place to coordinate a national plan. In this way, those who are ultimately responsible for the implementation will have an active role in its development.

2. Federal disaster relief or direct emergency relief is urgently needed to help states and localities most seriously impacted to provide the HIV prevention, treatment, care and support services now in short supply. The Commission strongly supports the efforts in Congress, now embodied in S.2240, to address this need. The resources simply must be provided now or we will pay dearly later.

3. Housing is an absolutely vital component of any comprehensive effort to address the multiple problems posed by HIV infection and AIDS. While the Commission recognizes that coordination between the state and local government, with input from community based organizations, is essential to effectively respond to the homeless crisis, we also believe the federal government must take the lead in providing the dollars needed to respond to this overwhelming, indeed catastrophic, problem.

4. Government restrictions imposed on the use of education and prevention funds are seriously impeding HIV control. They are clearly serving to prolong the HIV epidemic and should be removed.

5. Because the Americans with Disabilities Act (ADA) guarantees protection against discrimination for people with HIV infections and AIDS, the National Commission on AIDS strongly urges the U.S. House of Representatives to pass the ADA in a swift and timely manner. State and local governments should pass laws forbidding discrimination in areas not covered by the ADA or other federal statutes.

## Report Number Three:
## Research, the Workforce and the HIV Epidemic in Rural America
## August 1990

1. A comprehensive community-based primary health care system, supported by adequate funding and reimbursement rates, is essential for the care and treatment of all people, including people living with HIV infection and AIDS. The Commission highlighted this need in its first report and continues to believe that lack of access to primary care services provided by adequately trained primary care providers is undermining current efforts in HIV/AIDS research, prevention and treatment. The development of a comprehensive system with linkages to research protocols, existing community-based services, hospitals, drug treatment programs, local health departments, and long-term care facilities, based on a foundation of adequate support, is long overdue and should be a top priority for the federal government.

2. AIDS education and outreach services in rural communities should be expanded and designed to provide clear and direct messages about how HIV is and is not transmitted, and the kinds of behaviors that may place an individual at risk for HIV and other sexually transmitted diseases. Expansion of programs, resources and health care providers is also needed to respond to rural America's need for prevention and treatment programs that address the three epidemics of HIV infection, drug addiction and sexually transmitted diseases.

3. The NIH clinical trials program is in serious trouble. The limited number of enrollees in trials and the lack of demographic and geographic diversity of the participants threatens the success of the program and denies many people living with HIV infection and AIDS the opportunity to participate in experimental drug therapies. The academic health centers involved have not been as vigorous as one would hope in advancing these trials, nor has the NIH been vigorous in monitoring their performance. Aggressive efforts must be made to overcome the obstacles to participation of many who are under-represented. Success in this area can only be measured by increased participation in trials.

4. There is a desperate need for more research on the management of opportunistic infections, usually the cause of death for people with AIDS. The NIH simply must expand the level of research in this area. This expansion must not come at the expense of other research efforts and should be an integral part of a comprehensive AIDS research plan. This plan should outline the AIDS research priorities and goals for the entire NIH, and the resources needed to achieve them. The plan should be widely disseminated and should incorporate the views of persons living with HIV infection and AIDS.

5. There is a shortage of crisis proportions of health care providers capable and willing to care for people living with HIV infection and AIDS. This crisis will only get worse as the HIV epidemic continues into the 1990's. Action must be taken now to increase and improve the effectiveness of all programs designed to educate and retain practicing health care professionals, and to create incentives for providers to care for people in underserved areas. Existing programs such as the National Health Service Corps should be expanded. New programs such as those outlined in the Disadvantaged Minority Health Improvement Act (H.R. 3240) should be created. And, specific HIV/AIDS fellowships and training programs should be established and supported to prevent a crisis of greater magnitude.

6. Volunteers should be publicly recognized not only for the invaluable contribution they have made to people living with HIV infection and AIDS, but also for the way in which they fight fear and bigotry by fostering compassion and caring. The cost effective dollars needed to recruit, train, support and manage volunteers must be provided by the government and the private sector, and recognized as essential to our national response to the HIV epidemic.

## Report Number Four:
## HIV Disease in Correctional Facilities
## March 1991

1. The U.S. Public Health Service should develop guidelines for the prevention and treatment of HIV disease in all federal, state and local correctional facilities. Immediate steps should be taken to control the subsidiary epidemics of tuberculosis and sexually transmitted diseases. Particular attention should be given to the specific needs of women and youth within all policies.

2. Given the dearth of anecdotal and research information on incarcerated women, incarcerated youth and children born in custody, federal and state correctional officials should immediately assess and address conditions of confinement, adequacy of health care delivery systems, HIV education programs, and the availability of HIV testing and counseling, for these populations.

3. To combat the overwhelming effects which drug addiction, overcrowding and HIV disease are having on the already severely inadequate health care services of correctional systems nationwide, a program such as the National Health Service Corps should be created to attract health care providers to work in correctional systems.

4. The Department of Health and Human Services should issue a statement clarifying the federal policies on prisoners' access to clinical trials and investigational new drugs. In addition, the Food and Drug Administration, in conjunction with the Health Resources and Services Administration and the National Institutes of Health, should initiate an educational program directed toward informing inmates and health care professionals working in correctional facilities of the availability of investigational new drugs, expanded access programs, and applicable criteria for eligibility of prisoners in prophylactic and therapeutic research protocols.

5. Meaningful drug treatment must be made available on demand inside and outside correctional facilities. Access to family social services and nondirective reproductive counseling should also be made available with special emphasis on the populations of incarcerated women, youth and children born in custody.

6. Prison officials should ensure that both inmates and correctional staff have access to comprehensive HIV education and prevention programs. Particular attention should be paid to staff training on confidentiality and educating inmates about the resources available in the prison setting that may be employed to reduce the risk of infection.

7. The burden of determining and assuring standards of care has largely fallen to the courts, due, in part, to the failure of the public health authorities to take a leadership role in assuring appropriate standards of health care and disease prevention for our incarcerated populations. Bar associations and entities such as the Federal Judicial Center must, therefore, establish programs to educate judges, judicial clerks, and court officers about HIV disease.

## Report Number Five:
## The Twin Epidemics of Substance Use and HIV
## July 1991

1. Expand drug abuse treatment so that all who apply for treatment can be accepted into treatment programs. Continually work to improve the quality and effectiveness of drug abuse treatment.

2. Remove legal barriers to the purchase and possession of injection equipment. Such legal barriers do not reduce illicit drug injection. They do, however, limit the availability of new/clean injection equipment and therefore encourage the sharing of injection equipment, and the increase in HIV transmission.

3. The federal government must take the lead in developing and maintaining programs to prevent HIV transmission related to licit and illicit drug use.

4. Research and epidemiologic studies on the relationships between licit and illicit drug use and HIV transmission should be greatly expanded and funding should be increased, not reduced or merely held constant.

5. All levels of government and the private sector need to mount a serious and sustained attack on the social problems that promote licit and illicit drug use in American society.

## Report of The Working Group on Social/Human Issues
## April 1991

### Early Intervention and a Continuum of Care

*Increased efforts must be made to reach those who have historically been denied access to health care.* These efforts must include the development and enhancement of health care and social service providers within and by minority communities.

*Meaningful early intervention is more than the provision of AZT* or other drugs to those with HIV disease before they develop symptoms. Early intervention also entails psychological support, education and counseling, substance use treatment and social services.

*People living with HIV disease should be provided a continuum of care so that at every stage of illness they are cared for in the least restrictive setting possible,* preserving the greatest degree of independence. A responsive continuum of care will depend upon complex and intricate relationships among public health agencies, community-based and voluntary organizations, hospitals, nursing homes, and hospices.

*Comprehensive models of medical and psychosocial care for asymptomatic and mildly symptomatic individuals must be developed to ensure prevention and appropriate treatment.* Stronger links are needed among the HIV testing enterprise, the public health system, health care delivery systems, and social services. In particular, case management programs should be supported, and evaluated on an on-going basis.

*Spiritual counseling can be a critical component of care.* Spiritual counseling should be encouraged, not only in the hospital setting, but also in the outpatient and home care environment. Professional pastoral training programs, whether based in hospitals or graduate schools, should include curricula designed to prepare trainees to care for people living with HIV disease.

*Housing tailored to a range of medical and social needs is a critical part of the continuum of care for persons living with HIV disease. Congress should fund fully the AIDS Housing Opportunity Act of 1990.*

*There is a need for a consistent commitment to provision and expansion of drug treatment.* Attention must be given to the development of care relevant to HIV disease. High quality HIV education needs to be an integral part of all drug treatment programs. States should consider making this an explicit requirement of licensure for drug treatment programs.

### Delivering, Coordinating and Paying for Services

*Planning is key to developing a coordinated and effective response to HIV disease and people living with HIV disease must be included in planning activities. The planning process should be vigorously directed by the governmental agencies responsible for planning the communities' HIV response.* Such planning should include the private sector and members of affected communities. The receipt of government funding should be conditional upon the establishment of relationships between service providers and affected communities.

*Leadership is essential.* Leadership entails developing a vision of the response needed to meet the challenge of the HIV epidemic in a community, developing a plan to realize it, and accepting responsibility for its fulfillment.

*Continued and increased government and private support of voluntary and community-based organizations is critical.* Fledgling organizations established more recently to meet the needs of minority communities may require special technical assistance and financial support.

*Where the appropriate governmental entity is unable or unwilling to assume responsibility for planning and coordination, voluntary and community-based organizations should coordinate local efforts to avoid needless duplication and support the creation of mechanisms to provide national volunteer leadership, technical assistance, and resource sharing.* Volunteer efforts are too important to be fragmentary and competitive.

*Cooperation and accountability is necessary in coordinating the resources of a panoply of service providers and interest groups.* Government leaders, elected and appointed, must vigorously support the coordination effort.

The HIV disease caseload will continue to skyrocket, even if HIV disease loses its salience as a matter of public attention. Because of the disproportionate impact of HIV and its enormous impact on already suffering communities, *the federal government has the ultimate responsibility of assuring that a continuum of medical, psychological, and social services are available to people living with HIV disease.*

### Testing and Counseling

*It is inappropriate to create HIV antibody testing programs* to identify asymptomatic individuals for therapeutic interventions *unless they include plans to deliver and pay for appropriate follow-up services* for a substantial majority of those screened.

Presently available or foreseeable *therapeutic benefits cannot justify mandatory testing programs.* The prospect of therapeutic benefits is not a sufficient reason for abandoning long-standing principles of informed consent.

*Long-standing principles of confidentiality of medical information should not be abandoned, especially in light of the history of discrimination against persons with HIV disease.*

HIV antibody *testing must be accompanied by pre- and post-test counseling.* People with both positive and negative results should receive counseling. For those engaging in high-risk behaviors, whether infected or not, counseling must be viewed as a sustained process. More comprehensive standards are necessary to ensure consistently high quality counseling in a wide range of settings. More trained counselors are needed.

Despite the potential therapeutic benefit of HIV antibody testing, there exists an array of *educational and counseling interventions that can proceed independent of testing.* Much more needs to be done about education and prevention for women and people of color.

*Those who design and implement education and prevention programs must have the freedom to use explicit communication acceptable to the particular culture or group being addressed.* Sound principles of health education demand that messages which encourage behavior change be in language people understand and consistent with values that they accept.

*Legal protections against discrimination and unwarranted disclosures of HIV status are even more critical* as more at risk individuals are encouraged to undergo HIV antibody testing for early intervention. Mechanisms for the enforcement of the Americans with Disabilities Act and other antidiscrimination provisions must be put into place. In particular, state and local laws against discrimination must be rigorously enforced. Where such laws do not exist, or where they are weak, they need to be established and strengthened.

## Working Group on Federal, State and Local Responsibilities
## January 1990

1. Efforts in the public sector at all levels of government should be guided by broad policy goals. The Working Group suggested that the policy goals identified by the National Association of Counties Task Force on HIV Infection and AIDS could serve as a model for all levels of government. These goals are:
   1. to end the HIV epidemic through prevention, education and research;
   2. to assure access to treatment, care and support services for all persons with HIV infection;
   3. to protect the civil rights of all citizens; and
   4. to assure adequate funding for a continuum of HIV prevention, treatment, care and support services and HIV research through effective public sector-federal, state, and local government and private sector leadership and partnership.

2. Federal, state and local governments should develop comprehensive plans for implementing identified goals. These plans should be developed in response to the policy recommendations of the National Commission on AIDS with interagency government representation and private sector involvement, including community-based organizations and persons with HIV disease.

   The Working Group strongly recommended that the federal government should immediately develop a forceful comprehensive national HIV plan addressing prevention, education, treatment, care, support services, civil rights, research, and funding for these activities. The President should designate the Secretary of Health and Human Services to chair a cabinet-level Task Force to develop the national implementation plan. While the National Commission on AIDS fully intends to recommend policy goals for a national plan, the Commission believes it is essential that a Task Force be in place to enhance government-wide implementation of such a plan. In this way, those who are ultimately responsible for the implementation will have had an active role in its development, thus enhancing the likelihood of implementation. The Task Force should include each Department in the federal government and should solicit input from state and local governments and the private sector, including community-based organizations and persons with HIV disease.

3. The U.S. House of Representatives should, like the United States Senate, pass the Americans with Disabilities Act and state and local governments should pass laws forbidding discrimination in areas not covered by the Americans with Disabilities Act or other federal statutes.

4. Immediate action is necessary at the federal level to assist states, counties, and cities disproportionately impacted by the HIV epidemic. "Impact Aid"—disaster relief or direct emergency relief—is needed to assist states and localities in developing a continuum of HIV prevention, treatment, care, and support services.

5. The issues of Health Care Financing and Health Care and Social Service Organization and Delivery require a level of expertise and commitment of time that was not provided for in this working group session. The Working Group believes these issues would be best addressed by the full Commission.

6. Incentives at the federal, state and local level need to be created to recruit, retain and train human services personnel. The Working Group recommends that the federal government should support a National Health Service Corps approach to involving more primary care providers in the care of persons with HIV. Medicaid reimbursement rates for outpatient care should be augmented and all universities (public and private) should include HIV education in health professional education and training.

7. Federal, state and local government should have in place policies to encourage the development of housing programs that meet emergency, short-term and long-term needs of persons with HIV. Congress should support legislation to establish housing programs that provide

short-term and long-term housing with necessary support services. State legislation should encourage flexibility in developing alternative housing and residential settings. Localities need to address the "not-in-my-backyard" syndrome related to shelters and residencies, and work closely with neighborhood groups.

8. **Federal, state and local governments and community-based agencies need to develop more effective partnerships in HIV prevention, education and information.** The Working Group believes that federal restrictions on the use of education and prevention funds is counterproductive and prolongs the HIV epidemic. Restrictive legislative language appears to hinder states and localities and community-based agencies in providing the prevention message in ways that would reduce individual risk and limit the spread of HIV infection. Therefore, while states and localities should be accountable for the federal funds they receive, the use of these dollars for education and prevention programs should be flexible. Evaluation of these programs to determine what approaches work best is essential and these programs should be innovative, creative, and culturally respectful. Finally, since community-based organizations are at the heart of HIV education efforts, these agencies should be supported by all levels of government, including the provision of support for education and training of agency staff and organizational development assistance.

9. **The Working Group identified substance abuse prevention and treatment as a priority area but time did not permit specific recommendations to be made. The Working Group recommends that the full Commission address this issue.**

## APPENDIX C

## IMPLEMENTATION OF PRESIDENTIAL COMMISSION RECOMMENDATIONS

In its enabling legislation, the National Commission on AIDS was called upon to "[m]onitor the implementation of the recommendations of the Presidential Commission on the HIV Epidemic, modifying those recommendations as the Commission considers appropriate."[1] Monitoring the implementation of those recommendations has been a useful task for the National Commission, providing the National Commission with a number of insights into the federal response to the epidemic.

First, the recommendations were never used as the basis for a "national strategy" as was originally intended by the Presidential Commission. As Chairman Watkins expressed in his letter of transmittal to the President, "It is our hope, Mr. President, that you will . . . use our report as your national strategy. . . . "[2] Our failure as a nation to adopt the recommendations and to mobilize the necessary resources to respond to the recommendations indicates a glaring need for a national plan to coordinate the federal response to the HIV epidemic.

Second, the process of monitoring the recommendations highlighted how fragmented and decentralized the response to the epidemic has been on the part of the federal government. While some federal agencies have incorporated Presidential Commission recommendations into initiatives, these actions have taken place separate from other agencies within their Department and separate from other federal Departments.

Third, there is a need for evaluation of initiatives on the federal level. No clear evaluation tool was developed to gather useful information to monitor the response to the Presidential Commission recommendations.

### Historical Overview

In 1987 President Reagan established the Presidential Commission on the HIV Epidemic. After one year of hearings, the Presidential Commission produced a comprehensive report, which included 597 recommendations, and presented it to the President on June 27, 1988. The Institute of Medicine Committee for the Oversight of AIDS Activities, in a 1988 update of its book Confronting AIDS, stated that ". . . the commission has made major contributions to the public's understanding of HIV infection and AIDS and to the development of a compassionate and informed response to the epidemic. Guided by Admiral James D. Watkins' strong leadership and open-minded approach, the commission's focused attention has been effective in bringing diverse public and private resources to bear on a national problem."[3]

Within the 597 recommendations, the Presidential Commission identified a number of recommendations for immediate consideration by the federal government. Among these were: (1) passage of federal, state, and local antidiscrimination laws dealing with HIV as a disability in both the public and private sectors, (2) substance use treatment on demand, (3) federal protections for confidentiality, (4) health care worker recruitment and retention initiatives, (5) HIV education and prevention targeted to distinct populations as well as to the general public, (6) expansion of experimental drug trials, (7) health care financing reform, (8) ensuring the safety of the blood supply, and (9) support for international education and prevention efforts.

The Presidential Commission presented the recommendations to President Reagan, who then submitted them to his staff for evaluation.[4] In July of 1988 four staff members from the Department of Health and Human Services (HHS) were detailed to the White

House to assist the Director of the Drug Abuse Policy Office to prepare a response to the Presidential Commission recommendations. The staff created a form to standardize the response information and sent the report to all executive branch agencies, asking them to respond to recommendations that fell under their purview. As a result of their review, the staff determined that "40 percent of the commission's recommendations with a federal component have already been completed, are underway or are planned. Another 30 percent are under consideration as part of the FY 1990 agency budget plans."[5]

On August 2, 1988, President Reagan announced the adoption of a "10-point plan of action to advance the battle against AIDS and HIV consistent with the recommendations of the Presidential Commission on AIDS."[6] Of the 10 points included in the plan, 9 were rephrased Presidential Commission recommendations, including 6 of the top 20 recommendations. The 9 points were: (1) concern about substance abuse and its relation to HIV, (2) increase in community-based education and prevention, (3) acceleration of development, approval, and distribution of AIDS-related therapeutics, (4) support for international education and prevention efforts, (5) ensuring the safety of the blood supply, (6) health care financing reform, (7) adoption of "HIV in the workplace" guidelines, (8) creation of a special HIV emergency fund, and (9) review of Public Health Service plan for combating HIV and designation of a mechanism to follow up on the recommendations. The remaining point in the President's plan was a rephrased sentence from the introduction to the Commission report, affirming the President's commitment to allocation of adequate resources to combat the epidemic. The President also requested that the Attorney General identify the best way for the "federal government to provide direction and leadership to encourage non-discrimination for HIV infected individuals."[7]

The Office of the Director of Drug Abuse Policy was asked to update the recommendations again in September and December of 1988. In July of 1989, the Public Health Service's National AIDS Program Office (NAPO) updated the responses in a selected number of the report chapters in preparation for congressional hearings on AIDS treatment and health care.

At the time that the National Commission on AIDS was created HHS had taken responsibility for monitoring the response to the recommendations. The first involvement of the National Commission in the monitoring process came in working with NAPO to select a limited number of the recommendations to make the monitoring process more efficient. National Commission staff, with the assistance of NAPO staff, eliminated from consideration those recommendations that had been completed since the release of the report and selected those recommendations that highlighted gaps in the federal, state, and local responsibility, as well as those recommendations that the National Commission held to be priorities, including those that addressed prevention, treatment, research, and discrimination. The National Commission also eliminated those recommendations that were identified as statements of guidance rather than calls for specific action. Once the number of recommendations had been narrowed down, the National Commission asked NAPO to continue to serve as the liaison between the National Commission and the agencies responsible for action on the recommendations and to provide the National Commission with updates on progress being made on the recommendations. NAPO currently provides the National Commission with regular updates on those recommendations directed at HHS (a total of 113).

### Quality of Responses

On the standardized response forms developed by the White House staff, agencies are asked to determine whether or not the recommendations are the responsibility of the federal government, indicate whether they agree or disagree with the recommendations, and indicate whether their agency has taken any action as a result of the recommendations. According to the updated responses by HHS, the Administration agreed with the intent of 7 and has taken action on 8 of the 75 recommendations identified as the responsibility of the federal government. The 7 recommendations that the Administration agreed with and initiated action on included: (1) the signing of the Americans with Disabilities Act (ADA), (2) new initiatives on behalf of the National Institutes of Health to expand drug trials to include underrepresented groups, (3) a grant to the Network of Runaway and Youth Services to provide HIV education and prevention to homeless and runaway youth, (4) new demonstration projects to link primary care and drug treatment for HIV-infected individuals and their families, (5) implementation of Diagnostic Related Groups (DRGs) for Medicare-eligible HIV-infected patients, (6) state medical laboratory regulatory requirements proposed by the Health Care Financing Administration to be used as state model law, and (7) the extension of COBRA from 18 to 29 months to continue employer health insurance. The Administration disagreed with the intent of the eighth recommendation, that funds be appropriated to support home health care programs for underinsured people with HIV. The Administration took action on the eighth recommendation when Congress passed the HOPE Act (P.L. 100-607), which was signed into law by the President on November 4, 1988, and which authorized funds for the Health Resources and Services Administration to provide home health care to underinsured people with HIV.

It is unclear how much influence the Presidential Commission recommendations had on the implementation of these initiatives. It is probably safe to say that the recommendations played a role in identifying these issues as important and that individual agencies incorporated the recommendations of the Presidential Commission, along with those of other external and internal groups, into their own priority setting.

The remaining 67 responses to the recommendations identified as the responsibility of the federal government cite the continuation of ongoing federally sponsored projects as fully or partially addressing the recommendations.

Within the recommendations identified as not the reponsiblity of the federal government, there were three different categories of agency response:

1. The recommendation cited is not the responsibility of the federal government, rather the federal government is setting an example for state and local government and the private sector by incorporating the recommendation into federally based programs.
2. The recommendation is not the responsibility of the federal government, but the federal government has acknowledged the importance of the recommendation by including it as an incentive for state and local governments and the private sector to take the recommended action. Action on the recommendation becomes an incentive either by having the federal agencies include the recommendation as criteria for funding, or by providing funding and/or technical assistance specific to the recommendation.
3. The recommendation is not the responsibility of the federal government and the federal agencies are leaving it to state and local governments and the private sector to address the recommendation in their own projects.

### More Effective Process Needed for Evaluation

Unfortunately, the gathering of agency responses to the recommendations (even given the limited number of recommendations that the National Commission identified as priorities) has become a paper-driven rather that an evaluation-driven process. The most recent updates provided by the agencies cite "no change" as their response to the majority of the recommendations. Without comprehensive responses, the National Commission is unable to distinguish between those recommendations that have been successfully completed and those that warrant additional action. Additionally, the agency responses currently collected provide no information to the National Commission as to why those recommendations that have been planned or under consideration for three years have never been implemented.

### Action on Additional Presidential Commission Recommendations

A number of recommendations that the federal government acted on were not among the 113 identified by the National Commission. For example, federal agencies have taken action on Presidential Commission recommendations concerning workplace discrimination, housing discrimination, and immigration policy. The Presidential Commission asked that "[a]ll federal agencies should serve as a role model for the private sector by immediately adopting and implementing the employment policies for HIV infected workers described in the Office of Personnel Management guidelines." When President Reagan announced the adoption of his "10-point plan of action" against AIDS and HIV he echoed the Presidential Commission's recommendation by directing that "every federal agency adopt a policy based on the Office of Personnel guidelines on how to treat HIV infected persons in the workplace."[8] According to the Office of Personnel Management's evaluation of federal "AIDS in the workplace" policies, entitled "Implementation of AIDS policy at the Installation Level," only five federal agencies had not yet implemented "AIDS in the workplace" policies, and these five all reported having drafts currently in the approval process.[9]

The second recommendation stated that "federal antidiscrimination protection for persons with disabilities, including persons with HIV infection, should be expanded to cover housing that does not receive federal funds."[10] The Fair Housing Amendments Act of 1988 revised the Fair Housing Act to protect handicapped persons. The law itself does not contain specific language regarding HIV infection, but the Department of Housing and Urban Development, in its final rule implementing the law, included HIV in the listing of diseases that constitute a handicap."[11]

There has also been considerable federal action on issues pertaining to HIV and immigration policies. The Presidential Commission concurred with the World Health Organization's statement that "screening of international travelers for HIV would require an unjustified, immense diversion of resources from other critical programs of education, protection of the blood supply and care."[12] Prior to 1987, HHS had the power to designate the diseases to be included on the list of "dangerous contagious diseases" that served as warrants for the exclusion of persons wishing to enter the United States. In 1987 Congress added an amendment to the Supplemental Appropriations Act of 1987 (P.L. 100-71) that directed the President to add HIV infection to the "dangerous contagious diseases" list.

In 1989 a number of scientific, medical, and humanitarian organizations criticized the current U.S. visa practices.[13] In protest to these practices, expected participants to both the 6th International Conference on AIDS scheduled for San Francisco in June of 1990, and the 19th International Congress on Hemophilia scheduled for Washington, D.C. in August of 1990, announced their intention to boycott those meetings unless visa restrictions were changed. In December of 1989, the National Commission on AIDS released a background paper on AIDS and immigration and called upon the Department of State, the Department of Justice, and the Department of Health and Human Services to "conduct a comprehensive review of immigration policies as they regard communicable diseases, particularly HIV infection, focusing on public health needs."[14] In response to the

National Commission, as well as other concerned constituencies, Congress passed an immigration law that directed HHS to evaluate the list of "dangerous contagious diseases," renamed as the list of "communicable diseases of public health significance" as it relates to those entering the United States in late 1990.[15] In congressional testimony in 1990, Dr. William Roper, Director of the Centers for Disease Control, testified concerning the removal of HIV/AIDS and other sexually transmitted diseases (STDs) from the list of dangerous contagious diseases, and stated that

> *"[a]liens with these diseases can no longer be considered a significant public health threat to the United States. The sexually transmitted diseases proposed for deletion, as well as HIV infection, are not transmitted by casual contact, through the air, or from common vehicles—such as fomites, food, or water. Therefore an infected person in a common or public setting does not place another individual inadvertently or unwillingly at risk. Rather these diseases are primarily spread through voluntary exposure."*[16]

In January of 1991, HHS revised the list, deleting a number of STDs, including HIV infection, leaving "infectious tuberculosis" as the only "communicable disease of public health significance" for which aliens, including refugees, can be excluded from the United States.

As the June 1, 1991 deadline neared for decision about what list of diseases constituted grounds for exclusion, a new debate apparently arose within the Administration around the proposition that travelers should be dealt with separately from immigrants. One view in this discussion was that the costs of medical care for people with HIV infection or AIDS made this disease a communicable disease of public health significance that should result in exclusion of immigrants. The Commission has reviewed that issue and found that present immigration law deals extensively and in detail with such economic concerns in the exclusion of persons who wish to immigrate if they are likely at any time to become a public charge. To single out HIV disease in this economic context seems irrelevant and highly discriminatory.

The issuance on May 31, 1991 of an interim rule that extends the same travel and immigration restrictions as "communicable diseases of public health significance" that previously were classified as "dangerous contagious diseases" defies public health knowledge. This action perpetuates the misleading and discriminatory effects of prior HIV inclusion on an outdated list of diseases. This has had the additional, serious side effect of jeopardizing further important scientific meetings that are crucial to the efficient exchange of scientific information and progress in the midst of this accelerating pandemic.

## Conclusions

Over the course of the past two years, the National Commission on AIDS has submitted a series of recommendations to the President and Congress in addition to those included in this comprehensive report. Given the lack of federal response to the Presidential Commission recommendations, the National Commission has had to re-recommend a number of initiatives that were highlighted by the Presidential Commission. National Commission recommendations that overlap with the Presidential Commission recommendations include: (1) passage of antidiscrimination legislation, (2) intravenous drug use treatment on demand, (3) expansion of health care provider recruitment initiatives including the National Health Service Corps, (4) expansion of clinical trials to include underrepresented groups traditionally excluded from clinical research, such as people of color, (5) development of comprehensive care programs, (6) creation of a federal interagency mechanism to coordinate a national plan, and (7) funds for housing projects for people with HIV. The Congress and/or the President have taken some action to address all but two of these recommendations—treatment on demand and the creation of a federal interagency mechanism to coordinate a national plan. The National Commission will continue to monitor the response to its own recommendations in its third year and identify those areas of the national response that need additional initiatives.

The National Commission on AIDS has attempted to monitor the response to the Presidential Commission recommendations and in the process has brought attention to a number of deficiencies in the national response to the AIDS epidemic: lack of a comprehensive national plan, absence of federal leadership, and insufficient methods for evaluating HIV-related programs. As the successor to the Presidential Commission, the National Commission will continue to monitor the national response to the HIV epidemic and call for action from the federal as well as the state and local government and the private sector.

## References

1 National Commission on AIDS, Enabling Legislation, PL 100-607, November 4, 1988.
2 Report of the Presidential Commission on the Human Immunodeficiency Virus Epidemic, June 24, 1988, p. vii.
3 Institute of Medicine. 1988. *Confronting AIDS: Update 1988.* Washington, D.C.: National Academy Press.
4 "AIDS Drugs, Where are They?" 73rd Report of the Committee on Government Operations. Washington, D.C.: U.S. Government Printing Office.
5 White House, Office of the Press Secretary. 1988. Press release, August 2.
6 Ibid.
7 Report of the Presidential Commission on the Human Immunodeficiency Virus Epidemic, June 24, 1988, p. 112.
8 White House, Office of the Press Secretary. 1988. Press Release, August 2.
9 Communication with John Rogers, Employee Labor Relations, Office of Personnel Management; correspondence from Constance Newman, Director, Office of Personnel Management.
10 Report of the Presidential Commission on the Human Immunodeficiency Virus Epidemic, June 24, 1988, p. 107.
11 Congressional Research Service. AIDS Discrimination Issues: Legislative and Executive Actions, IB89125, February 28, 1991.
12 Report of the Presidential Commission on the Human Immunodeficiency Virus Epidemic, June 24, 1988, p. 156.
13 National Commission on AIDS. 1990. Press release, "Commission Calls for Changes in U.S. Visa and Immigration Policies." National Commission on AIDS Annual Report, p. 37.
14 National Commission on AIDS. 1990. "Resolution on U.S. Visa and Immigration Policy." National Commission on AIDS Annual Report, pp. 39–40.
15 National Commission on AIDS. 1990. Background paper "AIDS and Immigration: An Overview of United States Policy." National Commission on AIDS Annual Report, pp. 41–57.
16 Correspondence from Peter West, Senior Medical Advisor, Department of State, July 24, 1990.

## APPENDIX D

## PUBLIC LAW 100-607, NOVEMBER 4, 1988

National Commission on Acquired Immune Deficiency Syndrome Act. 42 USC 300cc note.

# Subtitle D—National Commission on Acquired Immune Deficiency Syndrome

### SEC. 241. SHORT TITLE.

This subtitle may be cited as the "National Commission on Acquired Immune Deficiency Syndrome Act".

### SEC. 242. ESTABLISHMENT.

There is established a commission to be known as the "National Commission on Acquired Immune Deficiency Syndrome" (hereinafter in this Act referred to as the "Commission").

### SEC. 243. DUTIES OF COMMISSION.

(a) General Purpose of the Commission.—The Commission shall carry out activities for the purpose of promoting the development of a national consensus on policy concerning acquired immune deficiency syndrome (hereinafter in this subtitle referred to as "AIDS") and of studying and making recommendations for a consistent national policy concerning AIDS.

(b) Succession.—The Commission shall succeed the Presidential Commission on the Human Immunodeficiency Virus Epidemic, established by Executive Order 12601, dated June 24, 1987.

(c) Functions.—The Commission shall perform the following functions:

(1) Monitor the implementation of the recommendations of the Presidential Commission on the Human Immunodeficiency Virus Epidemic, modifying those recommendations as the Commission considers appropriate.

Research and development. State and local governments.

(2) Evaluate the adequacy of, and make recommendations regarding, the financing of health care and research needs relating to AIDS, including the allocation of resources to various Federal agencies and State and local governments and the roles for and activities of private and public financing.

(3) Evaluate the adequacy of, and make recommendations regarding, the dissemination of information that is essential to the prevention of the spread of AIDS, and that recognizes the special needs of minorities and the important role of the family, educational institutions, religion, and community organizations in education and prevention efforts.

(4) Address any necessary behavioral changes needed to combat AIDS, taking into consideration the multiple moral, ethical, and legal concerns involved, and make recommendations regarding testing and counseling concerning AIDS, particularly with respect to maintaining confidentiality.

Civil rights.

(5) Evaluate the adequacy of, and make recommendations regarding, Federal and State laws on civil rights relating to AIDS.

(6) Evaluate the adequacy of, and make recommendations, regarding the capability of the Federal Government to make and implement policy concerning AIDS (and, to the extent feasible to do so, other diseases, known and unknown, in the future), including research and treatment, the availability of clinical trials, education and the financing thereof, and including specifically—

(A) the streamlining of rules, regulations, and administrative procedures relating to the approval by the Food and Drug Administration of new drugs and medical devices, including procedures for the release of experimental drugs; and

(B) the advancement of administrative consideration by the Health Care Financing Administration relating to reimbursement for new drugs and medical devices approved by the Food and Drug Administration.

(7) Evaluate the adequacy of, and make recommendations regarding, international coordination and cooperation concerning data collection, treatment modalities, and research concerning AIDS.

### SEC. 244. MEMBERSHIP.

(a) NUMBER AND APPOINTMENT.—

(1) APPOINTMENT.—The Commission shall be composed of 15 members as follows:

(A) Five members shall be appointed by the President—

President of U.S.

(i) three of whom shall be—

(I) the Secretary of Health and Human Services;

(II) the Administrator of Veterans' Affairs; and

(III) the Secretary of Defense;

who shall be nonvoting members, except that, in the case of a tie vote by the Commission, the Secretary of Health and Human Services shall be a voting member; and

(ii) two of whom shall be selected from the general public on the basis of such individuals being specially qualified to serve on the Commission by reason of their education, training, or experience.

(B) Five members shall be appointed by the Speaker of the House of Representatives on the joint recommendation of the Majority and Minority Leaders of the House of Representatives.

(C) Five members shall be appointed by the President pro tempore of the Senate on the joint recommendation of the Majority and Minority Leaders of the Senate.

(2) CONGRESSIONAL COMMITTEE RECOMMENDATIONS.—In making appointments under subparagraphs (B) and (C) of paragraph (1), the Majority and Minority Leaders of the House of Representatives and the Senate shall duly consider the recommendations of the Chairmen and Ranking Minority Members of committees with jurisdiction over laws contained in chapter 17 of title 38, United States Code (relating to veterans' health care), title XIX of the Social Security Act (42 U.S.C. 1901 et seq.) (relating to Medicaid), and the Public Health Service Act (42 U.S.C. 201 et seq.) (relating to the Public Health Service).

(3) REQUIREMENTS OF APPOINTMENTS.—The Majority and Minority Leaders of the Senate and the House of Representatives shall—

(A) select individuals who are specially qualified to serve on the Commission by reason of their education, training, or experience; and

(B) engage in consultations for the purpose of ensuring that the expertise of the 10 members appointed by the Speaker of the House of Representatives and the President pro tempore of the Senate shall provide as much of a balance as possible and, to the greatest extent possible, cover the fields of medicine, science, law, ethics, health-care economics, and health-care and social services.

(4) TERM OF MEMBERS.—Members of the Commission (other than members appointed under paragraph (1)(A)(i)) shall serve for the life of the Commission.

(5) VACANCY.—A vacancy on the Commission shall be filled in the manner in which the original appointment was made.

(b) CHAIRMAN.—Not later than 15 days after the members of the Commission are appointed, such members shall select a Chairman from among the members of the Commission.

(c) QUORUM.—Seven members of the Commission shall constitute a quorum, but a lesser number may be authorized by the Commission to conduct hearings.

(d) MEETINGS.—The Commission shall hold its first meeting on a date specified by the Chairman, but such date shall not be earlier than September 1, 1988, and not be later than 60 days after the date of the enactment of this Act, or September 30, 1988, whichever is later. After the initial meeting, the Commission shall meet at the call of the Chairman or a majority of its members, but shall meet at least three times each year during the life of the Commission.

(e) PAY.—Members of the Commission who are officers or employees or elected officials of a government entity shall receive no additional compensation by reason of their service on the Commission.

(f) PER DIEM.—While away from their homes or regular places of business in the performance of duties for the Commission, members of the Commission shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under sections 5702 and 5703 of title 5, United States Code.

(g) DEADLINE FOR APPOINTMENT.—Not earlier than July 11, 1988, and not later than 45 days after the date of the enactment of this Act, or August 1, 1988, whichever is later, the members of the Commission shall be appointed.

### SEC. 245. REPORTS.

(a) INTERIM REPORTS.—

(1) IN GENERAL.—Not later than 1 year after the date on which the Commission is fully constituted under section 244(a), the Commission shall prepare and submit to the President and to the appropriate committees of Congress a comprehensive report on the activities of the Commission to that date.

(2) CONTENTS.—The report submitted under paragraph (1) shall include such findings, and such recommendations for legislation and administrative action, as the Commission considers appropriate based on its activities to that date.

(3) OTHER REPORTS.—The Commission shall transmit such other reports as it considers appropriate.

(b) FINAL REPORT.—

(1) IN GENERAL.—Not later than 2 years after the date on which the Commission is fully constituted under section 244(a), the Commission shall prepare and submit a final report to the President and to the appropriate committees of Congress.

(2) CONTENTS.—The final report submitted under paragraph (1) shall contain a detailed statement of the activities of the Commission and of the findings and conclusions of the Commis-

sion, including such recommendations for legislation and administrative action as the Commission considers appropriate.

### SEC. 246. EXECUTIVE DIRECTOR AND STAFF.

(a) EXECUTIVE DIRECTOR.—

(1) APPOINTMENT.—The Commission shall have an Executive Director who shall be appointed by the Chairman, with the approval of the Commission, not later than 30 days after the Chairman is selected.

(2) COMPENSATION.—The Executive Director shall be compensated at a rate not to exceed the maximum rate of basic pay payable under GS–18 of the General Schedule as contained in title 5, United States Code.

(b) STAFF.—With the approval of the Commission, the Executive Director may appoint and fix the compensation of such additional personnel as the Executive Director considers necessary to carry out the duties of the Commission.

(c) APPLICABILITY OF CIVIL SERVICE LAWS.—The Executive Director and the additional personnel of the Commission appointed under subsection (b) may be appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and may be paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

(d) CONSULTANTS.—Subject to such rules as may be prescribed by the Commission, the Executive Director may procure temporary or intermittent services under section 3109(b) of title 5, United States Code, at rates for individuals not to exceed $200 per day.

(e) DETAILED PERSONNEL AND SUPPORT SERVICES.—Upon the request of the Commission for the detail of personnel, or for administrative and support services, to assist the Commission in carrying out its duties under this Act, the Secretary of Health and Human Services and the Administrator of Veterans' Affairs, either jointly or separately, may on a reimbursable basis (1) detail to the Commission personnel of the Department of Health and Human Services or the Veterans' Administration, respectively, or (2) provide to the Commission administrative and support services. The Secretary and the Administrator shall consult for the purpose of determining and implementing an appropriate method for jointly or separately detailing such personnel and providing such services.

### SEC. 247. POWERS OF COMMISSION.

(a) HEARINGS.—For the purpose of carrying out this Act, the Commission may conduct such hearings, sit and act at such times and places, take such testimony, and receive such evidence, as the Commission considers appropriate. The Commission may administer oaths or affirmations to witnesses appearing before the Commission.

(b) DELEGATION.—Any member or employee of the Commission may, if authorized by the Commission, take any action that the Commission is authorized to take under this Act.

(c) ACCESS TO INFORMATION.—The Commission may secure directly from any executive department or agency such information as may be necessary to enable the Commission to carry out this Act, except to the extent that the department or agency is expressly prohibited by law from furnishing such information. On the request of the Chairman of the Commission, the head of such department or agency shall furnish nonprohibited information to the Commission.

(d) MAILS.—The Commission may use the United States mails in the same manner and under the same conditions as other departments and agencies of the United States.

### SEC. 248. AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated for fiscal year 1989 $2,000,000, and such sums as may be necessary in any subsequent fiscal year, to carry out the purposes of this Act. Amounts appropriated pursuant to such authorization shall remain available until expended.

### SEC. 249. TERMINATION.

The Commission shall cease to exist 30 days after the date on which its final report is submitted under section 245(b). The President may extend the life of the Commission for a period of not to exceed 2 years.

## APPENDIX E

## COMMISSIONER BIOGRAPHIES

Chairman June E. Osborn, M.D., is Professor of Epidemiology and Dean of the School of Public Health at the University of Michigan; she is also Professor of Pediatrics and Communicable Diseases at the University of Michigan Medical School. She has served on numerous federal and non-federal committees, currently including the Global Commission on AIDS for the World Health Organization and the Robert Wood Johnson Foundation National Advisory Committee for the AIDS Health Services Project (Chair). Dr. Osborn has published extensively in the fields of virology, public health, and public policy. She earned her M.D. at Case Western Reserve University School of Medicine and did her pediatric residency at Harvard Hospitals. She is a member of both the American Academy of Pediatrics and the American Academy of Microbiology. In 1986 she was elected to membership in the Institute of Medicine of the National Academy of Sciences.

Vice Chairman David E. Rogers, M.D., completed his M.D. in 1948 at Cornell University and served an internship and residency at Johns Hopkins. Among his important appointments are those of Dean of Medicine and Vice President for Medical Affairs at Johns Hopkins University and Medical Director of the Johns Hopkins Hospital. Dr. Rogers was appointed the first Walsh McDermott University Professor of Medicine at the New York Hospital-Cornell University Medical Center in November 1986. For the 15 years preceding this appointment, Dr. Rogers was President of the Robert Wood Johnson Foundation in Princeton, New Jersey, the largest philanthropy devoting its resources to alleviating problems in the health care of Americans. Dr. Rogers has been very involved in the problems of AIDS, holding appointments as Chairman of the Advisory Council of the AIDS Institute of New York State, member of the Citizens Commission on AIDS of New York and New Jersey, Chair of the National Community AIDS Partnership, and Chair of the New York City Mayoral Task Force on AIDS.

Diane Ahrens is presently serving her 17th year as Commissioner of Ramsey County, Minnesota. She chaired the Human Services Steering Committee of the National Association of Counties (NACO) from 1986–1988 and in 1988 was appointed chair of NACO's task force on HIV/AIDS, which formulated recommendations for all counties regarding their role in addressing the HIV epidemic. She earned her Masters degree in Religion and Higher Education at Yale University.

Scott Allen, of Dallas, Texas, serves as a consultant for Homeward, Inc., and specializes in transitional care. He has conducted extensive research on the spiritual, ethical, and psychological dimensions of AIDS. He also provides direct pastoral care for people with AIDS, and is often called upon to act as a liaison between people with AIDS and their religious community and/or family. In addition, Reverend Allen is the founder and Co-Coordinator of the AIDS Interfaith Network of Dallas, Chairperson of the Subcommittee on State Responsibility of the Special Texas Legislative Task Force on AIDS, and Board Member of AIDS ARMS, a program to meet the special human needs of people with AIDS. Reverend Allen earned his Masters in Divinity from the Golden Gate Theological Seminary and served as pastor of the Pacific Baptist Church in California and as Minister of Education and Youth for the First Christian Church in Colorado Springs before joining the Christian Life Commission in 1985.

Harlon L. Dalton is a Professor at Yale Law School and a leading authority on legal issues generated by the AIDS epidemic. His AIDS-related publications include AIDS and the Law: A Guide for the Public, and "AIDS in Blackface." Mr. Dalton serves on the AIDS Interfaith Network in New Haven (chairperson), the Advisory Board of the Connecticut Consortium of AIDS, the Editorial Board of the AIDS Alert, and the New Haven Mayor's Task Force on AIDS. He earned his J.D. from Yale Law School.

Don C. Des Jarlais is currently the Director of Research for the Chemical Dependency Institute of Beth Israel Medical Center, Deputy Director for AIDS Research with Narcotic and Drug Research, Inc., and Professor of Community Medicine at Mount Sinai School of Medicine. He is an international leader in the fields of AIDS and intravenous drug use and during the past seven years has published over 100 scientific articles on the topics. He was the plenary speaker on intravenous drug use and AIDS at the 3rd, 4th, and 7th International Conferences on AIDS. He also serves as a consultant to various institutions, including the Centers for Disease Control, the National Institute on Drug Abuse, the National Academy of Sciences, and the World Health Organization. He is a Guest Investigator at Rockefeller University and a Visiting Professor of Psychology at Columbia University. Dr. Des Jarlais earned his Doctorate of Philosophy in Social Psychology from the University of Michigan.

Eunice Diaz, M.S., M.P.H., a private health consultant, is a nationally known expert and speaker on the subject of AIDS in the Hispanic community, and a former board member of AIDS Project Los Angeles. In addition, Ms. Diaz has served on numerous AIDS-related committees and panels, including the Los Angeles County Commission on AIDS, the Planning Committee for the Surgeon General's Conference on Pediatric AIDS, and most recently, the Task Force on AIDS of the Society for Hospital Marketing and Public Relations, American Hospital Association. Ms. Diaz earned her Master of Science and Master of Public Health at the Loma Linda University. She has received an honorary doctorate degree in humanities.

Donald S. Goldman is an attorney in private practice as a partner in the West Orange, New Jersey, law firm of Harkavy, Goldman, Goldman & Caprio. Active in The National Hemophilia Foundation and its chapters for over 25 years, he served as its Chairman from 1983 to 1984 and its President from 1984 to 1986. Mr. Goldman coordinated The National Hemophilia Foundation's efforts to improve the safety of the nation's blood supply, began many of its efforts in HIV risk reduction, and introduced initiatives to improve hemophilia and HIV service delivery to minorities. Currently he is also Vice President of the National Health Council, Inc. Mr. Goldman earned his J.D. from Rutgers University and has published and lectured widely on legal aspects of hemophilia, HIV infection, and other medical and ethical issues. He is a member of the Bar of New Jersey, the United States Court of Appeals for the Third Circuit, and the United States Supreme Court.

Larry Kessler is a founding member and Executive Director of the AIDS ACTION Committee of Massachusetts, New England's largest AIDS service organization. Beginning in 1983 as its only paid staff member, Kessler organized a corps of volunteers to combat the AIDS epidemic through education, service, advocacy, and outreach. He now oversees a staff of 75 full-time employees and more than 2,000 volunteers who provide support services to more than 1,400 men and women living with AIDS and HIV, and educational programs for health care providers, the public, and communities at risk of HIV infection. Kessler continues to play a leading role in advocating on the federal, state, and local levels for fair and effective AIDS policy and funding. He was an original member of the Massachusetts Governor's Task Force on AIDS and the Boston Mayor's Task Force on AIDS, under appointments by Governor Michael S. Dukakis and Mayor Raymond Flynn, respectively. Kessler is a founding board member of the former National AIDS Network and the AIDS ACTION Council in Washington, on whose board he continues to serve. Most recently, he was named to the Advisory Boards of the Harvard AIDS Institute and the National Leadership Coalition on AIDS. In 1987, Simmons College in Boston awarded him an Honorary Degree of Doctor of Human Services.

Charles Konigsberg, M.D., M.P.H., is a public health physician. He most recently served as Director of the Division of Health of the Kansas Department of Health and the Environment from October 1988 to August 1991. Previously he was the District Health Program Supervisor and Broward County Public Health Unit Director for the Department of Health and Rehabilitative Services in Fort Lauderdale. In Florida Dr. Konigsberg represented the county health official perspective on the Governor's AIDS Advisory Task Force. Dr. Konigsberg has also served as a consultant to the Centers for Disease Control and the U.S. Public Health Service in the development of HIV prevention and control strategies. He earned his M.D. from the University of Tennessee Center for the Health Sciences and his Master of Public Health in Community Health Administration from the University of North Carolina School of Public Health.

Belinda Ann Mason is a journalist and fiction writer who lives in rural Kentucky. In 1987 she was diagnosed with HIV and thereafter with AIDS. In 1988 she founded the Kentuckiana People With AIDS Coalition, the first organization of its kind in either Kentucky or Indiana. From 1989 to 1990 she served as President of the National Association of People With AIDS, and continues as its Chair Emeritus. Since 1990 she has served on the board of the AIDS Action Council in Washington, D.C. She is the recipient of numerous honors and awards including a distinguished leadership award from the Kentucky legislature.

J. Roy Rowland, M.D., is now serving his fourth term in the U.S. House of Representatives (Democrat, Georgia's Eighth Congressional District). As the only physician in Congress from 1985 to 1988, Congressman Rowland has provided leadership and insight on a number of health issues, such as infant mortality, rural health, the veterans' health system, and AIDS. His efforts on behalf of the AIDS community include sponsoring the legislation that authorized creation of the National Commission on AIDS and introducing a bill mandating study of AIDS among college students—an idea that was adopted administratively by the Centers for Disease Control. Congressman Rowland earned his M.D. from the Medical College of Georgia and maintained a family practice in central Georgia for three decades before pursuing a political career.

### Ex Officio

Richard B. Cheney was nominated by President Bush to be Secretary of Defense on March 10, 1989, was confirmed by the United States Senate on March 17, 1989, and took the oath of office on March 21, 1989. In August 1974, when Gerald R. Ford assumed the presidency, Mr. Cheney served on the Ford transition team, beginning in September 1974 as a Deputy Assistant to the President. In November 1975, he was named Assistant to the President and White House Chief of Staff, a position he held through the remainder of the Ford Administration, until January 1977. He returned to his home state of Wyoming in May 1977 to resume private life. Mr. Cheney was elected to Congress in November 1978. He was reelected in 1980, 1982, 1984, 1986, and 1988.

Edward J. Derwinski, President Bush's choice to become the first Secretary of the newly created cabinet-level Department of Veterans Affairs, was confirmed by the Senate on March 2, 1989 and sworn in on March 15, 1989. Secretary Derwinski directs the activities of the federal government's second largest department, responsible for a nationwide system of health care services and benefits programs for America's 27.3 million veterans. A member of the U.S. House of Representatives from 1959 to 1983, representing Illinois' Fourth Congressional District, he was the senior minority member of the House Foreign Affairs Committee, Post Office Committee, and Civil Service Committee. He played a major role in the passage of landmark civil service reform, postal service reorganization, and foreign service reform legislation.

Louis W. Sullivan, M.D., was sworn in as Secretary of Health and Human Services on March 10, 1989. As head of the Department of Health and Human Services, Dr. Sullivan oversees the federal agency responsible for the major health, welfare, food and drug safety, medical research, and income security programs serving the American people. Dr. Sullivan came to HHS from the Morehouse School of Medicine in Atlanta, Georgia. In July 1975, Dr. Sullivan became founding dean and director of the medical education program at Morehouse College. In July 1, 1981 when the School of Medicine became independent from Morehouse College he served as its first dean and president. In April 1985, the Morehouse School of Medicine was fully accredited and on May 17, 1985, the school awarded the M.D. degree to its first 16 graduates.

# APPENDIX F

## COMMISSION DOCUMENTS

For any of the following information please contact:
The National Commission on Acquired Immune Deficiency Syndrome
1730 K Street, N.W., Suite 815
Washington, D.C. 20006
(202) 254-5125.

Records are kept of all Commission proceedings and are available for public inspection at this address.

### Reports

First Interim Report to the President and the Congress: "Failure of U.S. Health Care System to Deal with HIV Epidemic." December 1989.

Working Group Summary Report on Federal, State, and Local Responsibilities. March 1990.

Second Interim Report to the President and the Congress: "Leadership, Legislation, and Regulation." April 1990.

Third Interim Report to the President and Congress: "Research, the Work Force, and the HIV Epidemic in Rural America." August 1990.

Annual Report to the President and the Congress. August 1990.

Fourth Interim Report to the President and the Congress: "HIV Disease in Correctional Facilities." March 1991.

Report of the Working Group on Social and Human Issues to the National Commission on AIDS. April 1991.

Fifth Interim Report to the President and the Congress: "The Twin Epidemics of Substance Use and HIV." August 1991.

### Statements

Support for Passage of the Americans with Disabilities Act. September 6, 1989.

Support for Increase in AIDS Funding in the FY '90 Appropriations Bill. September 19, 1989.

Support for the Goal of Treatment on Demand for Drug Users. September 26, 1989.

Support for Continued Funding of Research on Effectiveness of Bleach Distribution. November 7, 1989.

Endorsement of Principles and Objectives of Comprehensive AIDS Resources Emergency (CARE) Act of 1990. March 6, 1990.

Despite Debate Among Epidemiologist, HIV Epidemic Will Have Greater Impact in 1990s than 1980s. March 15, 1990.

Endorsement of Principles and Objectives of AIDS Prevention Act (H.R. 4470) and Medicaid AIDS and HIV Amendments Act of 1990 (H.R. 4080). May 11, 1990.

Endorsement of Principles and Objectives of the Ryan White CARE Act of 1990. March 6, 1991.

## Information on the Commission

Commission Fact Sheet

Individual Commissioner Biographies

Public Law 100-607 (Creation of the National Commission on AIDS)

For sale by the U.S. Government Printing Office
Superintendent of Documents, Mail Stop: SSOP, Washington, DC 20402-9328
ISBN 0-16-035859-0

ON AIDS
te 815
006